Supreme Court, U.S.
FILED

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No. __-____

IN THE
Supreme Court of the United States

ASS'N OF AM. PHYSICIANS & SURGEONS, INC., *ET AL.*,
PETITIONERS,

v.

FOOD & DRUG ADMIN., *ET AL.*,
RESPONDENTS.

On Petition for Writ of *Certiorari* to the U.S. Court of Appeals for the District of Columbia Circuit

PETITION FOR WRIT OF *CERTIORARI*

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QUESTIONS PRESENTED

Whether petitioners have standing to challenge approval by the Food & Drug Administration ("FDA") of the "Plan B" morning-after pill for distribution simultaneously as both a prescription drug and an over-the-counter drug?

Whether FDA lawfully may, by rule, compel administrative exhaustion before a plaintiff can challenge an FDA drug approval in court and, if so, which party bears the burden of proof on exhaustion?

Whether administrative exhaustion – if required – is satisfied by participation in FDA proceedings on the drug approval or is excused as futile based on FDA's consideration of the relevant issues in its drug approval or based on its opposition on the merits to petitioners' position during the litigation?

Whether, if petitioners lack standing, the courts below had subject-matter jurisdiction to reach the exhaustion issue?

Whether and how three-judge panels are bound by the prior decisions of three-judge or *en banc* panels in their circuits and how to address instances of intra-circuit splits in authority?

PARTIES TO THE PROCEEDING

Petitioners are the Association of American Physicians & Surgeons, Inc. ("AAPS"), Concerned Women for America ("CWA"), and Safe Drugs for Women ("SDW"). AAPS is a membership group primarily of physicians, and SDW is a membership group primarily of medical caregivers including physicians, pharmacists, and nurses. Although CWA also has members, CWA's members are not germane to this litigation because their non-informational injuries are too speculative to support standing, and CWA (*i.e.*, itself as a corporation) shares its members' informational injuries.

Respondents are the federal Food & Drug Administration ("FDA"), FDA's Commissioner in her official capacity and individual capacity under color of legal authority, the United States, and intervener Duramed Pharmaceuticals, Inc. ("Duramed"). Duramed manufactures the challenged drug.

Pursuant to this Court's Rule 29.6, petitioners state that AAPS, CWA, and SDW are non-profit corporations, and no publicly held company owns any interest in AAPS, CWA, or SDW.

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PETITION FOR WRIT OF *CERTIORARI*

The Association of American Physicians & Surgeons, Inc. ("AAPS"), Concerned Women for America ("CWA"), and Safe Drugs for Women ("SDW") respectfully petition this Court to issue a writ of *certiorari* to review the judgment of the U.S. Court of Appeals for the District of Columbia Circuit, which affirmed the district court's dismissal for lack of constitutional and prudential standing and for failure to exhaust the administrative remedy that regulations of respondent Food & Drug Administration ("FDA") purport to make mandatory.

OPINIONS BELOW

The court of appeals' unreported decision is reprinted in the Appendix ("App.") at 1a, and its unreported order denying cross dispositive motions is reprinted at App. 44a. The district court's decision is reported at 539 F.Supp.2d 4 and reprinted at App. 5a. The district court's unreported order denying the plaintiffs' post-judgment motions is reprinted at App. 38a.

JURISDICTION

The court of appeals issued its decision on November 27, 2009, and denied a timely filed petition for rehearing *en banc* on February 3, 2010 (order reprinted at App. 45a). The district court had jurisdiction under 28 U.S.C. §1331, and the court of appeals had jurisdiction under 28 U.S.C. §1291. This Court has jurisdiction under 28 U.S.C. §1254(1).

AUTHORITIES INVOLVED

The Appendix quotes 5 U.S.C. §704 and relevant excerpts from 21 U.S.C. §§353 and 355c, the Pediatric Research Equity Act of 2007, Pub. L. No. 110-85, 121 Stat. 866 (Sept. 27, 2007), FDA's

procedural regulations (21 C.F.R. §§10.3, .25, .35, .45, .85), and the regulations implementing 21 U.S.C. §353 (21 C.F.R. §310.200). The authorities fall into three primary areas:

1. ***Rx-OTC Dichotomy.*** In 1951, the Durham-Humphrey Amendments ("DHA") to the Federal Food, Drug and Cosmetic Act, 21 U.S.C. §§301-399a ("FFDCA"), resolved confusion between the drugs eligible for sale only by prescription ("Rx") and those eligible for sale over the counter ("OTC"). In pertinent part, the amendments added FFDCA §353(b)(4) to create a strict dichotomy between Rx drugs on the one hand, and OTC drugs on the other. 21 U.S.C. §353(b)(4). The legislative history confirms the statute's plain text: "over-the-counter drugs are forbidden to bear a label containing [the Rx] caution statement." S. REP. NO. 82-946, at 10 (1951). This litigation challenges FDA's first-ever approval for a drug for dual Rx-OTC distribution.

2. ***Rulemaking to Remove Drug from Rx Requirements.*** The DHA also added FFDCA §353(b)(3) to establish the regulatory process for moving Rx drugs to OTC status by rulemaking, 21 U.S.C. §353(b)(3), and added FFDCA §353(b)(1) to provide that holding a drug limited to Rx use for dispensing without a prescription constitutes misbranding. 21 U.S.C. §353(b)(1).

3. ***Data Required for Adolescent Uses.*** The Pediatric Research Equity Act of 2003, PUB. L. NO. 108-155, 117 Stat. 1936 (2003), and the Pediatric Research Equity Act of 2007, PUB. L. NO. 110-85, Title IV, 121 Stat. 823, 866-76 (2007) ("PREA"), supplement the data that drug manufacturers must submit to support their products when those products will be used by "pediatric" populations. The

term "pediatric" includes adolescents both above and below eighteen years of age. First Am. Compl. ¶92.[1] Like the other data that manufacturers submit to support drug approvals, these data guide the label language, 21 U.S.C. §355c(g)(2), and result in informational postings on FDA's website. 21 U.S.C. §355c(h)(1).

STATEMENT OF THE CASE

Petitioners filed this action to challenge both the substance and procedure of FDA's approval of a Supplemental New Drug Application ("SNDA") for age-bifurcated, dual Rx-OTC distribution of

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[1] Like FDA's Pediatrics Rule, 63 Fed. Reg. 66,632 (1998), on which PREA is based, PREA does not specify or define rigid age ranges for "pediatric" subpopulations. In promulgating its final rule, FDA accepted comments that opposed the rigid age ranges of the proposed rule and adopted a flexible approach that considers stages of development. 63 Fed. Reg. at 66,650-51. In addition to considering pediatric populations aged up to 21 years old in its rulemaking, 63 Fed. Reg. at 66,651, the Pediatrics Rule expressly covered adolescents as well as neonates, infants, and children. 63 Fed. Reg. at 66,668 (former 21 C.F.R. §201.23(a)). Moreover, puberty extends beyond the eighteenth birthday for a significant pediatric subpopulation. First Am. Compl. ¶92 (*citing* Leon Speroff & Mark A. Fritz, *Clinical Gynecologic Endocrinology and Infertility*, at 370 (Lippincott Williams & Wilkins 7th ed. 2005); FDA, "International Conference on Harmonisation; E11: Clinical Investigation of Medicinal Products in the Pediatric Population," 65 Fed. Reg. 19,777, 19,780 (2000); FDA, "International Conference on Harmonisation; E11: Clinical Investigation of Medicinal Products in the Pediatric Population; Availability," 65 Fed. Reg. 78,493 (2000); FDA, "Guidance for Industry: E11 Clinical Investigation of Medicinal Products in the Pediatric Population," at 9 (Dec. 2000)).

levonorgestrel tablets, 0.75 mg (hereinafter "Plan B"). The operative complaint includes eight counts:

I Plan B violates FFDCA's safety and efficacy requirements for OTC drugs;

II Plan B unlawfully bears dual Rx-OTC labeling;

III Plan B is unlawfully bifurcated by age and lacks the data required by PREA;

IV Plan B's dual Rx-OTC labeling unlawfully creates a third "behind-the-counter" drug category;

V FDA failed to convene an APA rulemaking for its changed drug policies;

VI FDA failed to convene an FFDCA rulemaking to remove Plan B from Rx requirements;

VII FDA approved Plan B under unlawful senatorial pressure; and

VIII FDA's exhaustion rule is unlawful.

First Am. Compl. at ¶¶96-136 (Court of Appeal Joint Appendix ("CAJA") 121-29). Petitioners seek *vacatur* of FDA's SNDA and related declaratory relief.

Because FDA declined to certify the administrative record, petitioners moved the district court to compel FDA to do so and filed a notice of the availability of portions of the record on FDA and Government Printing Office websites. CAJA 199-206. Without requiring FDA to certify the record, the district court granted the FDA and Duramed motions to dismiss for lack of standing and failure to exhaust administrative remedies. App. at 6a. In doing so, the district judge relied on representations by Duramed's counsel that "no administrative record of the FDA's consideration of [petitioners"] arguments exists ... because [petitioners] have never

submitted those challenges to the FDA." App. at 33a-34a. On August 22, 2008, the district court denied petitioners' timely filed motion under Rules 15, 52(c), 59(c), and 60(b), and this appeal followed.

This action concerns the same FDA approval at issue in *Tummino v. Hamburg*, No. 05-0366-ERK-VVP (E.D.N.Y.), where the new administration declined to appeal the court's order to extend OTC status for Plan B from "18 and older" to "17 and older." *Tummino v. Torti*, 603 F.Supp.2d 519 (E.D.N.Y. 2009). The relief that petitioners seek here is consistent with the *Tummino* order to treat 17-year-olds the same as those 18 or older, except that petitioners here would remove OTC distribution for everyone, whereas *Tummino* seeks to extend OTC distribution downward. Significantly, the *Tummino* plaintiffs ultimately seek to extend Plan B's OTC status to all ages, without regard for PREA compliance. Perhaps even more significantly, the *Tummino* judgment that FDA declined to appeal was entered without subject-matter jurisdiction under the standards of *Summers v. Earth Island Institute*, 129 S.Ct. 1142, 1151 (2009). Specifically, the Court denied FDA's motion to dismiss (filed under the previous administration) on standing based on pleadings, but never found that the plaintiffs had standing on the merits. *Tummino*, 603 F.Supp.2d at 539 ("plaintiffs are responding to a motion to dismiss, so their allegations in the complaint must be accepted as true for purposes of standing"). As a result of FDA's unexplainable decision not to appeal an obviously baseless ruling, minors are exposed to a powerful hormonal drug, with abortifacient properties, notwithstanding the lack of required safety data.

Factual Background

In 1999, FDA approved an Rx-only NDA for Plan B, in which FDA granted a one-time waiver to the then-applicable requirements for pediatric data. First Am. Compl. ¶67 (CAJA 112). In 2003, Plan B's sponsor (now Duramed) sought to switch Plan B to OTC distribution, but FDA had safety concerns about young women. CAJA 66-67, In response to FDA "not-approvable letters" based on safety concerns for younger women, Duramed proposed age bifurcation (*i.e.*, Rx for younger women, OTC for older women), and FDA found that approach to present "difficult and novel issues," on which it issued an advance notice of proposed rulemaking ("ANPRM") in which petitioners and their members filed comments that covered the issues raised in this litigation. CAJA 66, 404-34; First Am. Compl. ¶72 (CAJA 114).

During this process, two Senators publicly announced a hold on Acting Commissioner von Eschenbach's nomination as FDA Commissioner until FDA took final action on Plan B, First Am. Compl. ¶73 (CAJA 114); CAJA 436-37 (¶8), and one of them conditioned release of her hold on FDA's approving Plan B for OTC distribution. CAJA 436-37 (¶8). Because FDA could not approve Plan B for OTC distribution without additional data on younger women, and Duramed had serially declined to submit such data, FDA had only two options: capitulation or an extended rulemaking (delaying Senate confirmation).

On the eve of the confirmation hearing, FDA suddenly and without reasoned explanation resolved the "difficult and novel issues" and approved Plan B for age-bifurcated Rx-OTC distribution. In his

testimony to Congress that day, Dr. von Eschenbach acknowledged that FDA had considered the public comments in approving Duramed's SNDA and, indeed, could not have approved the SNDA without the public comments. CAJA 441-44 (¶¶3-9).

Regulatory Background

In 1954, FDA promulgated §310.200(b)'s first predecessor (former 21 C.F.R. §1.108(c)) expressly pursuant to §503(b)(3). 19 Fed. Reg. 7347, 7347-48 (1954). In 1963, FDA proposed and finalized §311.200(b)'s direct predecessor (former 21 C.F.R. §130.101(b)) expressly pursuant to §503(b)(1) and §503(b)(3). 28 Fed. Reg. 1449 (1963); 28 Fed. Reg. 6377 (1963). In pertinent part, and consistent with the plain statutory text, the 1954 and 1963 versions both expressly required a rulemaking to remove a new drug from prescription requirements under §503(b)(1), even if the "petition" that triggered the rulemaking came to FDA via an SNDA or on FDA's own initiative. *See* 19 Fed. Reg. at 7347-48 (promulgated 21 C.F.R. §1.108(c)); 28 Fed. Reg. at 6385 (promulgated 21 C.F.R. §130.101). Specifically, in both 1954 and 1963, the final regulation provided as follows:

> A proposal to exempt a drug from the prescription-dispensing requirements of section 503(b) (1) (C) [now §503(b)(1)(B)] of the act may be initiated by the Commissioner or by any interested person. Any interested person may file a petition seeking such exemption, stating reasonable grounds therefor, which petition may be in the form of a supplement to an approved new-drug application. Upon receipt of such a petition, or on his own initiative at any time, the

> Commissioner will publish a notice of proposed rule making and invite written comments. After consideration of all available data, including any comments submitted, the Commissioner may issue a regulation granting or refusing the exemption[.] Whenever the Commissioner concludes... that granting or refusing the exemption requires a more thorough development of the facts than is possible in a written presentation, he may call a public hearing for that purpose.... As soon as practicable after the completion of the hearing, the final regulation granting or refusing the exemption shall be issued[.]

21 C.F.R. §130.101(b) (1964); *accord* 21 C.F.R. §1.108(c) (1955); *accord* 21 C.F.R. §310.200(b) (1976). Thus, from 1954 through 1976, FDA could not tenable interpret §310.200(b) as it does not to allow amending an SNDA via order, rather than rulemaking.

In the interval, FDA has adopted only one substantive amendment to §310.200(b), as part of its rulemaking in the mid-1970s to adopt its uniform rules of administrative practice. 40 Fed. Reg. 40,682, 40,769 (1975) (proposed amendment to §310.200(b)); 42 Fed. Reg. 4680, 4714 (1977) (promulgated amendment to §310.200(b)).[2] As FDA's rulemaking

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[2] When it recodified its regulations in 1974, FDA plainly designated "Old section" §130.101 as "New section" §310.200. 39 Fed. Reg. 11,680 (Mar. 29, 1974). In a 1977 recodification, FDA amended §310.200(b) to change the reference from the original rules of practice (former 21 C.F.R. pt. 2) to the

(Footnote cont'd on next page)

record demonstrates, adopting the uniform rules for administrative practice did not alter the type of administrative action required to remove drugs from the Rx requirements of §503(b)(1). Instead, the notice of proposed rulemaking merely provided that "Section 310.200(b) would be revised to replace the procedure now set out in that provision with a reference to Part 2." 40 Fed. Reg. at 40,716. The mere elimination of §310.200(b)'s rulemaking process in deference to the new general-purpose Part 2 process does not suggest a *sub silentio* intent to do away with rulemakings altogether. *U.S. v. Wilson*, 290 F.3d 347, 359-60 (D.C. Cir. 2002) (drafter "unlikely to intend any radical departures from past practice without making a point of saying so"). Instead, FDA would simply convene §503(b)(3)'s required rulemakings under the general provisions of Part 2, not the specific provisions of §310.200(b).

FDA's rulemaking to add §310.200(e) on OTC-panel procedures confirms that, in 1976, FDA interpreted §310.200(b) consistently with the statute (and opposite its current position):

> [T]he Commissioner described the two procedures by which a prescription drug ingredient may lawfully be marketed for OTC use. Ingredients limited to prescription

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recodified ones (current 21 C.F.R. pt. 10). 42 Fed. Reg. 15,673, 15,674 (Mar. 22, 1977) ("Section 310.200(b) is amended by changing the reference to 'Part 2' to read 'Part 10'"). Technical amendments in 2007 changed citations to §505(b)(1)(C) to the now-current §505(b)(1)(B). 72 Fed. Reg. 15,043 (Mar. 30, 2007).

> use under section 503(b)(1)(C) of the [FFDCA] may acquire OTC status by a petition submitted pursuant to the procedures set forth in § 310.200 []; the OTC drug review process provides another procedure.

41 Fed. Reg. 32,580, 32,581 (1976) (citations omitted). As indicated, "the procedures set forth in § 310.200" clearly contemplated that FDA would act "by regulation," even if the "petition" came to FDA in the form of an SNDA or if FDA acted on its own initiative. 21 C.F.R. §310.200(b) (1976). Moreover, the regulations expressly and currently limit Rx-to-OTC switches to §310.200(b)'s petition process and §330.13's monograph process: "Any drug limited to prescription use under section 503(b)(1)(B) of the act remains so limited until it is exempted as provided in paragraph (b) or (e) of this section." 21 C.F.R. §310.200(a). To change either its interpretation of its regulation (*i.e.*, to switch the required procedures from a rulemaking to an order) or its regulations themselves, FDA would need to undertake a rulemaking. 21 C.F.R. §10.85(d)(1), (e); *Motor Veh. Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 42 (1983) (course change requires reasoned analysis beyond that required to act in the first instance). FDA has not taken any *lawful* final action to amend its procedures.

Consistent with the DHA's plain text and legislative history, FDA's implementing regulations also provide that "*Prescription legend not allowed on exempted drugs.* The use of the prescription caution statement quoted in [§]503(b)(4) of the act, in the labeling of a drug exempted under the provisions of

this section, constitutes misbranding." 21 C.F.R. §310.200(d) (emphasis in original).

REASONS TO GRANT THE WRIT

The writ of *certiorari* should be granted both to resolve splits among the courts of appeal on jurisdictional issues and to exercise this Court's supervisory authority in matters of importance both to review of FDA drug approvals and to the lower courts' exercise of their authority:

(1) To address the lower courts' deviation from this Court's and other circuits' decisions on informational, competitive, and procedural standing (Sections I.A.1, I.A.2, and I.A.4, respectively);

(2) To address a split in circuit authority on the jurisdictional versus non-jurisdictional basis of dismissal for failure to exhaust administrative remedies and the allocation of the burden of proof (Section II.B);

(3) To exercise this Court's supervisory authority over the lower courts' improper exercise of jurisdiction to reach a merits issue (the validity of FDA's rule requiring administrative exhaustion), if indeed the petitioners lack standing (Section IV); and

(4) To address a split in circuit authority and to exercise this Court's supervisory authority over the extent to which three-judge panels are bound by the holdings of prior three-judge panels in intra-circuit splits (Section V).

In addition to these important legal issues, this litigation also presents important policy issues on the review of FDA action and has important safety implications on the exposure of minors to a powerful

and untested hormonal drug with abortifacient properties.

I. PETITIONERS HAVE STANDING

As in any federal litigation, constitutional and prudential standing are threshold issues here. Given that the lower courts also reached the merits on FDA's exhaustion regulation, however, the Court should grant the writ of *certiorari* even if petitioners lack standing. Thus, in addition to being a threshold issue, standing is also a fork in the road. If petitioners have standing, the Court should consider whether FDA can require exhaustion and whether petitioners have satisfied exhaustion (Sections II-III, *infra*). If petitioners lack standing, the Court should consider why (and on what jurisdiction) the lower courts upheld FDA's exhaustion rule (Section IV, *infra*).

A. Constitutional Standing

At its constitutional minimum, standing involves a tripartite test of a cognizable injury to the plaintiff, caused by the defendant, and redressable by the court. *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 561-62 (1992). Injury need not be to economic or comparably tangible because an "identifiable trifle" suffices. *U.S. v. Students Challenging Regulatory Agency Procedures (SCRAP)*, 412 U.S. 669, 690 n.14 (1973). While direct injuries pose "little question" of causation or redressability, plaintiffs have a heightened showing when government action affects third parties, who then cause injury. *Defenders of Wildlife*, 504 U.S. at 561-62. Standing can be expanded by third-party or associational standing and narrowed by prudential concerns such as the zone-of-interests test.

Associations – including associations of associations – can litigate on behalf of individual members if those members have standing, their interests are germane to the association, and nothing requires individual participation. *N.Y. State Club Ass'n, Inc. v. New York*, 487 U.S. 1, 9 (1988). Further, associations can assert third-party standing based on the relationships between members and third parties, and the plaintiff need not identify a *specific* third party because *potential* customers suffice. *Craig v. Boren*, 429 U.S. 190, 194-95 (1976); *Carey v. Population Serv., Int'l*, 431 U.S. 678, 683 (1977). Once a plaintiff has established *constitutional* standing, that plaintiff may rely on third-party standing to satisfy the merely *prudential* zone-of-interest test. *Carey*, 431 U.S. at 682-86.

If petitioners establish standing for any *one* substantive count for vacating the SNDA (*e.g.*, Counts I-IV, VI, and VII), that would suffice for *all six* substantive counts. *Duke Power Co. v. Carolina Envtl. Study Group, Inc.*, 438 U.S. 59, 78-81 (1978) (standing doctrine has no nexus requirement outside taxpayer standing); *DaimlerChrysler Corp. v. Cuno*, 547 U.S. 332, 353 & n.5 (2006) ("once a litigant has standing to request invalidation of a particular agency action, it may do so by identifying all grounds on which the agency may have failed to comply with its statutory mandate"). Finally, if they have substantive standing, petitioners also have procedural standing (Counts V and VIII).

1. Informational Standing

The lower courts denied informational standing for several reasons, including remarkably that FFDCA does not create a right in accurate drug labeling information. App. 19a. The courts failed to

conform their reasoning to this Court's precedents and the cases from other circuits.

FFDCA creates rights in accurate labeling information by criminalizing misbranding, defined as "labeling [that] is false or misleading in any particular." 21 U.S.C. §352(a). Petitioners have an even greater claim to informational standing than the tester who had standing in *Havens Realty Corp. v. Coleman,* 455 U.S. 363, 373 (1982). The statutes are parallel in their requiring truthful information, *compare* 21 U.S.C. §352(a) *with* 42 U.S.C. §3604(d), but she "expected to receive false information regarding the availability of homes for purchase," "had no intention of buying a home," and still "was held to have standing." *Alston v. Countrywide Financial Corp.*, 585 F.3d 753, 763 (3rd Cir. 2009). In any event, FDA's binding preambles foreclose FDA's denying that physicians have rights in labeling. 44 Fed. Reg. 37,434, 37,435 (1979) ("prescription drug labeling is intended to provide physicians with a clear and concise statement of the data and information necessary for safe and effective use of the drug").[3] Medical professionals plainly have informational rights in drug information. *Cf.*

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[3] *See also id.* at 37,436 ("This statutory scheme for drug labeling is intended to provide physicians... with the information they need to prescribe a drug under conditions that maximize the drug's effectiveness and minimize its risks"); 43 Fed. Reg. 4214, 4213 (1978) ("When a pharmacist, physician, nurse, or other person dispenses the drug... to the patient, he... bears the responsibility for providing... the [patient] labeling.... [L]abeling serves primarily as an informational adjunct to the physician-patient encounter and is intended to reinforce and augment oral information given by the physician").

Heartwood, Inc. v. U.S. Forest Service, 230 F.3d 947, 952 n.5 (7th Cir. 2000) (National Environmental Policy Act provides process to "provide stakeholders with information necessary to monitor agency activity"); *American Canoe Ass'n, Inc. v. City of Louisa Water & Sewer Comm'n*, 389 F.3d 536, 542 (6th Cir. 2004). The lower court's contrary reasoning is baseless.

Statutorily required labeling is particularly germane to pharmacists, whose lot the DHA intended to improve by eliminating the ambiguity between Rx and OTC drugs. Here, Plan B's unprecedented dual Rx-OTC labeling falsely suggests that pharmacists lawfully may dispense that product OTC to adults, notwithstanding §503(b)(1)'s prohibition. As regulated professionals, the standing doctrine does not require pharmacists to violate their profession's ethical requirements by dispensing a misbranded drug. *See NRDC v. SEC*, 606 F.2d 1031, 1042 (D.C. Cir. 1979) (investors who wish to behave in "ethically sound manner" have standing to redress "arguabl[e] impair[ment]" from "lack of [allegedly required] information"). The courts below have no basis for declining to follow this circuit precedent.

The lower courts also incorrectly reasoned that the information-providing statute must have a cause of action for denial of information, *compare* App. at 19a *with Pub. Citizen v. Dep't of Justice*, 491 U.S. 440, 449-51 (1989) (finding informational standing under Federal Advisory Committee Act, which lacks any cause of action). That is not required.

The lower courts also incorrectly reasoned that petitioners could not show redressability

because *vacatur* would leave them without any label changes. *Compare* App. at 21a *with FEC v. Akins*, 524 U.S. 11, 25 (1998). As *Akins* recognized, *vacatur* would put the parties back in the position they should have been in all along, which provides enough redress even if FDA (or Duramed) *potentially could* take action on remand that would leave plaintiffs no better off. Remand redresses injury "even though the agency (like a new jury after a mistrial) might later, in the exercise of its lawful discretion, reach the same result for a different reason." *Id.; see also* Section I.A.4, *infra* (relaxed showing of redressability for procedural injuries). Specifically, *vacatur* would mean that Duramed again has a pending SNDA, which (if petitioners prevail) FDA can approve only by rulemaking.

Similarly, *vacatur* would make the Plan B SNDA subject to PREA, which FDA inappropriately waived: "[a]n assessment pending on or after the date that is 1 year prior to the date of the enactment of this Act shall be subject to the tracking and disclosure requirements established under [21 U.S.C. §355c], as in effect on or after such date of enactment." PUB. L. NO. 110-85, §402(b)(2), 121 Stat. 866, 875 (Sept. 27, 2007). That would open up even more information that petitioners seek. 21 U.S.C. (1951) §355c(g)(2), (h)(1)-(2). That too provides sufficient basis for informational standing.

2. Competitive Standing

Although the complaint frames physicians' injury as exposure to unlawful competition, First Am. Compl. ¶¶19-20 (CAJA 96), the district court required proof of lost revenue. App. at 23a. Under the unambiguous law of the D.C. Circuit, plaintiffs can plead exposure to competition as an injury

distinct from lost sales: the "injury claimed here is not lost sales, *per se;* ... [r]ather the injury claimed is exposure to competition," *Bristol-Myers Squibb Co. v. Shalala*, 91 F.3d 1493, 1499 (D.C. Cir. 1996); *Shays v. F.E.C.*, 414 F.3d 76, 86 (D.C. Cir. 2005) ("increased competition represents a cognizable Article III injury"); *La. Energy & Power Auth. v. FERC*, 141 F.3d 364, 367 (D.C. Cir. 1998) ("[courts] have not required litigants to wait until increased competition actually occurs"). "[Plaintiffs] sufficiently establish their constitutional standing by showing that the challenged action authorizes allegedly illegal transactions that have the clear and immediate potential to compete with petitioners' own sales." *Assoc. Gas Distribs. v. FERC*, 899 F.2d 1250, 1259 (D.C. Cir. 1990). To rule otherwise the courts below had to ignore the foregoing binding precedent. See Section V, *infra*, on three-judge panels' obligation to follow circuit precedent.

The circuits are in agreement with the law of the D.C. Circuit as stated by the foregoing decisions. *See, e.g., Canadian Lumber Trade Alliance v. U.S.*, 517 F.3d 1319, 1333-34 (Fed. Cir. 2008) (analyzing competitive standing even when plaintiff is not "textbook candidate"); *Peoples Gas, Light & Coke Co. v. U.S. Postal Service*, 658 F.2d 1182, 1194 (7th Cir. 1981) (recognizing competition between gas and electric power); *Adams v. Watson*, 10 F.3d 915, 920-25 (1st Cir. 1993); *cf. Seven-Up Co. v. Coca-Cola Co.*, 86 F.3d 1379, 1383 (5th Cir. 1996) ("indirect or even non-competitors may also have standing under the Lanham Act"). The decisions below conflicted not only with binding circuit law, but also with the law in the other circuits.

Whatever a "textbook candidate" might mean to the Federal Circuit, it does not mean that competitive standing applies only to like entities such as physician-to-physician or manufacturer-to-manufacturer competition.[4] Any economic textbook recognizes both supplementary and complimentary goods. Physicians give away access to Plan B prescriptions, but charge for office visits. With OTC Plan B, pharmacists allow free visits to their offices, but charge a markup for access to Plan B (*i.e.*, they charge customers more than Duramed charges the pharmacist). The market is "access to Plan B," and physicians and pharmacists compete in it.

3. Authorizing Illegal Conduct

Petitioners argue (and for standing, courts must accept) that dual Rx-OTC Plan B is misbranded when held for OTC sales. Even if petitioners are wrong about the Rx-OTC merits, the prior Rx-only Plan B certainly could not lawfully be sold OTC. The courts below reasoned that the challenged competition and patient activity is not traceable to FDA's approval because it depends on unfettered third-party choices. App. at 23a. But patients' actions are not truly unfettered when FDA's challenged approval is the action that makes

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[4] This Court's precedents long ago foreclosed limiting competitive standing to like entities. *Arnold Tours, Inc. v. Camp*, 400 U.S. 45, 46 (1970) ("[w]hen national banks begin to provide travel services for their customers, they compete with travel agents no less than they compete with data processors when they provide data-processing services to their customers"); *Alton R. Co. v. U.S.*, 315 U.S. 15, 18-20 (1942) (railroads versus truckers).

those choices possible. Without FDA's approval, that conduct would be unlawful, and no pharmacist would offer Plan B for OTC distribution.

Under binding D.C. Circuit precedent, injury is "fairly traceable to the administrative action contested... if that action *authorized* the conduct or established its legality." *Tel. & Data Sys., Inc. v. FCC*, 19 F.3d 42, 47 (D.C. Cir. 1994) (emphasis added); *Animal Legal Def. Fund v. Glickman*, 154 F.3d 426, 441-42 (D.C. Cir. 1998) (*en banc*). *On the merits* it is indisputable that Plan B's OTC distribution is unlawful because dual Rx-OTC Plan B is misbranded when held for OTC sale. 21 U.S.C. §353(b)(1), (4); 21 C.F.R. §310.200(d). Even if Plan B were not misbranded when held for OTC sale, FDA's SNDA authorized pharmacists to distribute Plan B without a prescription, which they previously could not lawfully do. *Simon v. E.K.W.R.O.*, 426 U.S. 26, 45 n.25 (1976) (private injury traceable to agency action if injurious conduct "would have been illegal without that action"); *see, e.g.*, M.C.L.A. §§333.16215, 333.17708(2)-(3), 333.17745(12) (limiting the dispensing of prescription drugs in Michigan to various types of physicians and dentists and to staff under their supervision); M.C.L.A. §333.17764 (criminalizing sale of misbranded drug). This is another example of the larger issue addressed in Section V, *infra*, of lower courts' nullifying circuit precedent.

4. Procedural Standing

The decisions below conflict with another important aspect of constitutional standing: the relaxation of immediacy and redressability for plaintiffs who suffer procedural injury where the procedure is "designed to protect [the] threatened

concrete interest of his that is the basis of [such plaintiffs'] standing." *Defenders of Wildlife*, 504 U.S. at 573 n.8; *Defenders of Wildlife*, 504 U.S. at 572 n.7. Here, Congress recognized that the Rx-OTC distinction affects consumers, pharmacists, physicians, and drug manufacturers, S. REP. NO. 82-946, at 2 (quoted *supra*); H.R. REP. 82-700, at 9 (same), so §503(b)(3)'s required rulemaking obviously is a procedure designed to protect petitioners' interests.

Consistent with this Court's holdings, the circuits recognize the relaxed showing on immediacy and redressability. *See, e.g., Cantrell v. City of Long Beach*, 241 F.3d 674, 682 (9th Cir. 2001); *Nulankeyutmonen Nkihtaqmikon v. Impson*, 503 F.3d 18, 27-28 (1st Cir. 2007); *cf. Rosebud Sioux Tribe v. McDivitt*, 286 F.3d 1031, 1040 (8th Cir. 2002) ("procedural standing can substitute for constitutional standing"). Indeed, even the D.C. Circuit recognizes that "[i]f a party claiming the deprivation of a right to notice-and-comment rulemaking under the APA had to show that its comment would have altered the agency's rule, section 553 would be a dead letter." *Sugar Cane Growers Co-op. of Fla. v. Veneman*, 289 F.3d 89, 95 (D.C. Cir. 2002). Nonetheless, the decisions below relaxed neither immediacy nor redressability. Instead (and contrary precedent under both procedural and competitive standing), the courts required a showing of actual loss, App. 23a, and faulted petitioners for not showing that *vacatur* of the SNDA would redress their labeling concerns. App 21a. Of course, forcing FDA and Duramed into the rulemaking that the DHA require in the first place would provide an opportunity to raise petitioners'

issues with FDA. *Akins*, 524 U.S. at 25. Procedural standing does not require more.

B. Prudential Standing

Standing's "zone of interest" test is a prudential doctrine that asks "whether the interest sought to be protected by the complainant is *arguably* within the zone of interests to be protected ... by the statute." *N.C.U.A. v. First Nat'l Bank & Trust, Co.*, 522 U.S. 479, 492 (1998) (emphasis and alteration in original). Petitioners are within the zone of interests, which is inapposite to *ultra vires* actions, and are "suitable challengers" even if outside the zone. At the outset, however, the merely prudential zone is irrelevant because FDA legislatively waived it.

1. FDA Waived the Zone Test

Unlike constitutional standing, prudential tests are subject to legislative waiver, *Ctr. for Auto Safety v. NHTSA*, 793 F.2d 1322, 1335-36 (D.C. Cir. 1986), and FDA's legislative rulemakings waive standing: "It is the opinion of the Commissioner that every citizen has standing in the courts to contest any action of the agency, and that no objection relating to such standing will be interposed by the agency in such cases." 40 Fed. Reg. 40,689 (1975); *accord* 42 Fed. Reg. 4688 (1977). Because FDA unquestionably has authority for legislative rules, 21 U.S.C. §371(a), and unquestionably binds itself to its preambles, 21 C.F.R. §10.85(d)(1), (e), any sub-constitutional limit on standing is waived.

2. Petitioners Meet Zone Test

The courts below held physicians' competitive and economic injuries outside the zone, App. at 25a & n.4, without recognizing that the test "struck the

balance in a manner favoring review, but excluding those would-be plaintiffs not even arguably within the zone of interests to be protected or regulated by the statute." *Clarke v. Securities Industry Ass'n*, 479 U.S. 388, 396-97 (1987). "[N]ot meant to be especially demanding," "it suffic[es] to establish reviewability" under the test if "the general policy implicit in the [relevant statutes] was 'apparent' and that 'those whose interests are directly affected by a broad or narrow interpretation of the Acts are easily identifiable.'" *Clarke*, 479 U.S. at 399-400 & n.14.

Physicians' competitive interests vis-à-vis pharmacists are plainly "affected by a broad or narrow interpretation" of the DHA. *NCUA*, 522 U.S. at 499 ("Although... respondents' objectives in this action are not eleemosynary in nature, ... that, too, is beside the point"). Indeed, Congress expressly considered physicians *beneficiaries* of relaxing Rx requirements when truly not required (*e.g.*, for aspirin), 97 Cong. Rec. 9328 (1951) (Reps. Gwinn and O'Hara), and both committee reports recognized physicians among those affected. *See* S. REP. NO. 82-946, at 2 (quoted *supra*); H.R. REP. 82-700, at 9 (same). Thus, physicians' injuries are in the zone.

More significantly, Plan B's dual Rx-OTC labeling denies pharmacists their statutory right to labeling that clearly indicates "which drugs may be sold on prescription and which drugs may be sold freely over the counter," which the House floor manager considered the first question behind the DHA legislation. 97 Cong. Rec. at 9321 (Rep.

Wolverton).[5] That right is the dead center of the DHA's zone of interests, which FDA violated by approving a label that falsely suggests that Plan B is lawful for OTC sales. By denying pharmacists the single most important information that the DHA required, FDA puts pharmacists in the untenable position of violating state and federal law and their professional obligations, which Congress expressly intended to spare them.

3. Zone for *Ultra Vires* Acts

Because standing assumes plaintiffs' merits views – here, that FDA lacks authority for a dual Rx-OTC product, which is misbranded – Circuit law should have either held the zone-of-interest test inapplicable or applied the zone from the overriding constitutional issues raised by a lawless agency. *Haitian Refugee Ctr. v. Gracey*, 809 F.2d 794, 812 (D.C. Cir. 1987); *accord Chiles v. Thornburgh*, 865 F.2d 1197, 1211 (11th Cir. 1989). By acting outside its

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[5] *See id.* at 9328 ("druggists throughout this country have figuratively been swinging on the jailhouse door, because... the druggist oftentimes is unable to know whether he is violating the law by selling a drug... without a prescription") (Rep. Carlyle); *id.* at 9330 ("druggists of this country want this thing nailed down so that they will not be slammed in jail" and calling clear Rx vs. OTC labeling "belling the cat") (Rep. Roberts); *id.* at 9336 (report lists over 100 druggists "convicted for over-the-counter sales of drugs, many... selling them innocently") (Rep. Beckworth); *id.* at 9343 (same); *id.* ("Under the present law he does not know whether the drugs he sells over the counter are in violation of the law") (Rep. Thornberry); *id.* at 9344-45 ("he does not know whether he is violating the law if he sells the drug over the counter... What the druggist is seeking is certainty") (Rep. Williams).

delegation, FDA makes law without the constitutional process for making law, violating "the separation-of-powers principle, the aim of which is to protect... the whole people from improvident laws." *Metro. Washington Airports Auth. v. Citizens for the Abatement of Aircraft Noise*, 501 U.S. 252, 271 (1991); *Ass'n of Data Processing Serv. Org'ns v. Camp*, 397 U.S. 150, 153 (1970) (test asks whether plaintiff is "arguably within the zone of interests to be protected or regulated by the statute or constitutional guarantee in question"). Because FDA acted outside its statute and its own regulations, the narrow zone considered by the courts below should not shield FDA's unlawful conduct.

This Court has not addressed the theory in the D.C. and Eleventh Circuits that agencies' *ultra vires* conduct either renders the zone of interests inapposite or raises the zone of larger constitutional protections than the narrow laws under which agencies take their challenged actions. It should.

4. Suitable Challengers

Even if not the intended beneficiaries, petitioners can satisfy the zone of interests as "suitable challengers" if their "interests... [are] sufficiently congruent with those of the intended beneficiaries that [they] are not more likely to frustrate than to further the statutory objectives." *First Nat'l Bank & Trust Co. v. N.C.U.A.*, 988 F.2d 1272, 1275 (D.C. Cir. 1993). Although the district court found physicians' competitive injuries contrary to the statutory purpose, App. 25 n.4, that finding could preclude suitable-challenger standing only for the safety issue, not for the various bright-line statutory violations (*e.g.*, §503(b)'s Rx-OTC dichotomy/rulemaking requirement and PREA's data

requirements) under binding Circuit precedent: "the *Hazardous Waste Treatment Council* line of cases is inapposite when a competitor sues to enforce a *statutory demarcation, such as an entry restriction,* because the potentially limitless incentives of competitors [are] channeled by the terms of the statute into suits of a limited nature brought to enforce the statutory demarcation." *Honeywell Int'l, Inc. v. EPA,* 374 F.3d 1363, 1370 (D.C. Cir. 2004) (citing cases) (emphasis added, alteration in original), *withdrawn on part on other grounds,* 393 F.3d 1315 (D.C. Cir. 2005); *N.C.U.A.,* 988 F.2d at 1278; *Scheduled Airlines Traffic Offices, Inc. v. D.O.D.,* 87 F.3d 1356, 1360-61 (D.C. Cir. 1996) ("Sato's interests cannot diverge from the... statute[:...] Either the funds at issue in this case are covered by the statute or they are not"). Under binding Circuit precedent, if physicians have constitutional standing, they also have prudential standing because "entry-like restrictions" are not subject to manipulation.

This is another example of the larger issue addressed in Section V, *infra,* of district judges and three-judge panels nullifying circuit precedent.

II. FDA CANNOT REQUIRE OR PROVE EXHAUSTION

Although its *optional* citizen-petition process is commendable, 21 C.F.R. §10.25(a) ("interested person *may* petition [FDA] to issue, amend, or revoke a regulation or order"), FDA's *mandatory* exhaustion regulation is unlawful. *Id.* §10.45(b) ("request that [FDA] take or refrain from taking any... action *must* first be the subject of a final administrative decision based on a petition submitted under §10.25(a)").

Moreover, even if lawful, FDA should bear the burden of proof, which it did not meet here.

A. FDA Cannot Require Exhaustion

Assuming *arguendo* that FDA has authority to require exhaustion by rule, notwithstanding that FFDCA does not require exhaustion, the FDA rule cannot insulate any and all FDA action from review. For example, exhaustion does not apply for the issues that are "solely one[s] of statutory interpretation" where "the proper interpretation [was] certainly not a matter of [agency] discretion." *McKart v. U.S.*, 395 U.S. 185, 197-99 (1969). Similarly, the rule that "courts ordinarily should not interfere with an agency until it has completed its action" does not apply where the agency "has clearly exceeded its jurisdiction." *McKart*, 395 U.S. at 194. Because the DHA, the DHA's legislative history, and FDA's own regulations prohibit dual Rx-OTC labeling, for example, FDA lacks jurisdiction to approve a dual Rx-OTC label.

Technically, "'[e]xhaustion' applies where a claim is cognizable in the first instance by an administrative agency alone." *U.S. v. Western Pac. R. Co.*, 352 U.S. 59, 63 (1956). While that includes the decision on whether to approve a drug or what the labeling should say, it does not apply to *how* FDA approves a drug. If §503(b)(3) requires a rulemaking, petitioners need not first ask FDA to follow the law. *Cf.* 28 U.S.C. §1651(a). On FDA's duty to act by rulemaking, courts are the first *and* final arbiter.

To the extent that FDA has authority to require exhaustion by rule, FDA cannot require it *unless* the disputed agency action remains inoperative during any intra-agency appeals. 5

U.S.C. §704. Far from meeting §704, FDA regulations expressly provide the *opposite*. 21 C.F.R. §10.35(d) ("action taken by an interested person... will [not] stay or otherwise delay any [FDA] administrative action").

When challenging "final agency action," an APA plaintiff has no duty to exhaust optional administrative remedies *unless* the disputed agency action remains inoperative during that further administrative process. 5 U.S.C. §704 ("*Except as otherwise expressly required by statute,* agency action otherwise final is final for the purposes of this section... *unless the agency otherwise requires by rule and provides that the action meanwhile is inoperative,* for an appeal to superior agency authority") (emphasis added).

> Agencies may avoid the finality of an initial decision, first, by adopting a rule that an agency appeal be taken before judicial review is available, and, second, by providing that the initial decision would be "inoperative" pending appeal. Otherwise, the initial decision becomes final and the aggrieved party is entitled to judicial review.

Darby v. Cisneros, 509 U.S. 137, 152 (1993) (emphasis added). "Courts are not free to impose an exhaustion requirement as a rule of judicial administration where the agency action has already become 'final' under [§704]." *Darby,* 509 U.S. at 153-54. If the D.C. Circuit has trouble with this clear restriction, then circuits with a lighter APA caseload also would benefit from this Court's clarification.

B. FDA Did Not Prove Exhaustion

Separate from the question of whether FDA can require exhaustion is the question of which party bears the burden of proof. This also relates to the question of whether exhaustion is an affirmative defense under FED. R. CIV. P. 12(b)(6) or an element of jurisdiction under FED. R. CIV. P. 12(b)(1). If the former, defendants bear the burden of proof; if the latter, plaintiffs bear the burden of proof.

When a statute does not require exhaustion, "courts are guided by congressional intent in determining whether application of the [exhaustion] doctrine would be consistent with the statutory scheme" and "should not defer the exercise of jurisdiction under a federal statute unless it is consistent with that intent." *Coit Independence Joint Venture v. Federal Sav. & Loan Ins. Corp.*, 489 U.S. 561, 579-80 (1989) (interior quotations omitted); *Weinberger v. Salfi*, 422 U.S. 749, 765 (1975) ("doctrine of administrative exhaustion should be applied with a regard for the particular administrative scheme at issue"). Here, nothing in FFDCA counsels for deferring jurisdiction to review FDA's procedural and substantive violations of DHA and PREA. Accordingly, as with other instances where the statute is silent, courts should follow "the usual practice under the Federal Rules[, which] is to regard exhaustion as an affirmative defense." *Jones v. Bock*, 549 U.S. 199, 212 (2007). That usual practice allocates the burden of proof to defendants under FED. R. CIV. P. 12(b)(6).

Relying on the unsworn statements of defendants' counsel that the SNDA and public processes were not joined, the district court committed clear error in holding (without the record)

that "FDA has [not] ha[d] the opportunity to apply its expertise and [develop] a record." App. at 34a. That plainly violates the law of the D.C. Circuit:

> [T]he district court appears to have relied on the parties' written or oral representations to discern the basis on which the FDA acted. Surely that was not sufficient.

Am. Bioscience, Inc. v. Thompson, 243 F.3d 579, 582 (D.C. Cir. 2001). But "[t]here is some uncertainty regarding whether a failure to exhaust administrative remedies is properly brought in a Rule 12(b)(1) motion, as a jurisdictional defect, or in a Rule 12(b)(6) motion for failure to state a claim." *Hall v. Sebelius*, __ F.Supp.2d __, 2009 WL 3088821, 6-7 (D.D.C. 2009) (citing cases);[6] *compare Michael Reese Hosp. & Medical Ctr. v. Thompson*, 427 F.3d 436, 443 (7th Cir. 2005) ("exhaustion of administrative remedies is a prerequisite of subject matter jurisdiction") *and Dalton v. City of Las Vegas*, 282 Fed.Appx. 652, 656 (10th Cir. 2008) ("APA requires exhaustion of administrative remedies before federal jurisdiction will lie") *with Western Radio Services Co. v. Qwest Corp.*, 530 F.3d 1186, 1196 (9th Cir. 2008) ("[APA] finality is a jurisdictional requirement, while some statutory exhaustion

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[6] Failure to exhaust administrative remedies resembles "a defense for lack of jurisdiction in one important sense: Exhaustion of administrative remedies is a matter[ ] in abatement, and ordinarily [does] not deal with the merits." *Bryant v. Rich*, 530 F.3d 1368, 1374 (11th Cir. 2008) (alterations in original, interior quotations omitted).

requirements may not be jurisdictional").[7] This Court should clarify the issue.

III. LACK OF EXHAUSTION DOES NOT REQUIRE DISMISSAL

Assuming *arguendo* that FDA's exhaustion rule validly applies, that still would not justify dismissal. First, petitioners exhausted FDA's administrative remedy. Second, exhaustion would be futile, both because FDA in fact considered petitioners' issues and because FDA opposed them on the merits in this litigation.

A. Petitioners Satisfied Exhaustion

FDA defines "[i]nterested person" as "a person who submits a petition *or comment or objection...* in an informal or formal administrative proceeding." 21 C.F.R. §10.3(a) (emphasis added).[8] Consistent with §503(b)(3), a manufacturer's SNDA for an Rx-to-OTC switch is a "petition" under §10.25(a). 21 C.F.R. §§10.25(a)(1) (including forms under 21 C.F.R. §314.50 among the forms that constitute a "petition"), 310.200(b) ("Any interested person may

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[7] *See also Bangura v. Hansen*, 434 F.3d 487, 493-94 (6th Cir. 2006) (exhaustion is jurisdictional if mandated by Congress); *Doe v. Oberweis Dairy*, 456 F.3d 704, 711-12 (7th Cir. 2006) (same); *Mahon v. U.S. Dept. of Agriculture*, 485 F.3d 1247, 1262 (11th Cir. 2007) (distinguishing between statutes that require exhaustion jurisdictionally and statutes that merely codify the common law); *Impson*, 503 F.3d at 33-34 (distinguishing mandatory statutory exhaustion from jurisdiction).

[8] The suggestion that a party may seek review only of "*its* challenge," App. at 34a (emphasis in original), would create the anomaly that commenters *opposing* a petition cannot challenge FDA's *granting* the petition without re-petitioning for *vacatur*.

file a petition seeking such exemption, which petition may be pursuant to Part 10 of this chapter, or *in the form of a supplement to an approved new drug application*"), 314.50 ("Applications and *supplements to approved applications* are required to be submitted in the form... required *under this section*") (emphases added). Duramed's §314.50 application unquestionably is a petition under §10.25(a).

Moreover, the "procedures" that FDA may take "[i]n reviewing a petition" expressly include "[a] *Federal Register* notice requesting information and views." 21 C.F.R. §10.30(h)(3). FDA requested comments in two notices here, 68 Fed. Reg. 66,113 (2003); 70 Fed. Reg. 52,050 (2005), and petitioners participated in both. Because both notices qualify as a "*Federal Register* notice requesting information and views" about issues raised by Duramed's SNDA, petitioners unquestionably are "interested persons" under §10.3(a). *Cf. Stauber v. Shalala,* 895 F.Supp. 1178, 1188-89 (W.D. Wisc. 1995) (finding response to FDA request for comments on NDA satisfies exhaustion).

Because they commented on *Federal Register* notices that FDA issued on Duramed's SNDA "petition" – and because FDA considered the comments[9] in deciding to proceed with Duramed's SNDA, Section III.B *infra* – petitioners satisfy both the letter and the spirit of FDA's regulations. By

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[9] Petitioners raised all of the relevant issues presented here. CAJA 405-30 (safety, efficacy, Rx-OTC dichotomy with no "third drug" category, age restrictions unlawful, PREA, APA rulemaking), 432 (§503(b)(3) rulemaking).

rejecting this argument, the courts below split with *Stauber*, the only other relevant authority.

B. Consideration of Petitioners' Issues in SNDA Makes Exhaustion Futile

Assuming *arguendo* that exhaustion applies and is not satisfied, exhaustion still would provide no basis for dismissal. FDA considered the issues that petitioners want to raise here, so requiring FDA to re-consider them again would be futile.

Then-Acting Commissioner von Eschenbach testified to Congress that: (1) FDA analyzed the public comments with "an internal process;" (2) he "engaged in the analysis of that [internal process];" (3) both he and career FDA staff concluded that the public comments provided "overwhelming evidence" that FDA could proceed without rulemaking and could "accommodate the bifurcation" within FDA's "current regulatory framework;" (4) the public comments made it possible to decide the SNDA (*i.e.*, the SNDA was unapprovable without the public comments); and (5) the public comments helped set the bifurcation age at 18 on both enforceability and safety. CAJA 442-44 (¶¶6-9), 447-51; *see also* 340-41 (74:24-75:4, FDA admission at oral argument); 68 (FDA acknowledges SNDA's reliance on public comments). Thus, contrary to the district court's baseless findings, App. 34a, FDA did apply its expertise, a written record exists, and the SNDA and public processes clearly were "joined."

Under an *en banc* decision of the D.C. Circuit, that should suffice because courts "should not dismiss [*nonparticipating* plaintiffs if] the agency in fact considered the statutory issue raised in the [complaint]." *NRDC v. EPA*, 824 F.2d 1146, 1150-

1152 (D.C. Cir. 1987) (*en banc*). It "obviously would have been futile for [plaintiff] to have petitioned the agency... to repeal" agency actions "where [agency] had just determined that the [actions] in question were still necessary in the public interest." *Fox Tel. Stations, Inc. v. F.C.C.*, 280 F.3d 1027, 1040 (D.C. Cir. 2002). In summary, the law in the D.C. Circuit is clear that exhaustion does not require petitioning an agency to re-reject an argument, and this is another example of the larger issue addressed in Section V, *infra*, of lower courts' nullifying circuit precedent.

C. Rule 12(b)(6) Motion on Petitioners' Positions Makes Exhaustion Futile

Assuming *arguendo* that exhaustion applies, is not satisfied, and was not otherwise futile, exhaustion still would provide no basis for dismissal. In the district court, FDA opposed petitioners on the merits under FED. R. CIV. P. 12(b)(6), which means that FDA has "predetermined the issues," even if FDA's SNDA did not. As the *McCarthy* Court stated, "in view of Attorney General's submission that the challenged rules of the prison were 'validly and correctly applied to petitioner,' requiring administrative review through a process culminating with the Attorney General 'would be to demand a futile act.'" *McCarthy v. Madigan*, 503 U.S. 140, 148 (1992) (quoting *Houghton v. Shafer*, 392 U.S. 639, 640 (1968)). Again, exhaustion does not require petitioning agencies to re-reject an argument.

IV. IF PETITIONERS LACK STANDING, RULING ON EXHAUSTION IS *DICTA*

Even when the parties below do not dispute jurisdiction, "no action of the parties can confer

subject-matter jurisdiction upon a federal court." *Insurance Corp. of Ireland, Ltd. v. Compagnie des Bauxites de Guinee*, 456 U.S. 694, 702 (1982). Indeed, "every federal appellate court has a special obligation to satisfy itself not only of its own jurisdiction, but also that of the lower courts in a cause under review, even though the parties are prepared to concede it." *FW/PBS, Inc. v. City of Dallas*, 493 U.S. 215, 231 (1990) (interior quotations omitted). "And if the record discloses that the lower court was without jurisdiction [an appellate] court will notice the defect." *Id.* (interior quotations omitted). In such cases, appellate courts "have jurisdiction on appeal, not of the merits but merely for the purpose of correcting the error of the lower court in entertaining the suit." *Steel Co. v. Citizens for a Better Environment*, 523 U.S. 83, 95 (1998) (interior quotations omitted).

Technically, of course, this is not a case where "action of the parties [purports to] confer subject-matter jurisdiction upon a federal court." *Bauxites de Guinee*, 456 U.S. at 702. The petitioners insist that there is jurisdiction, and the respondents insist that there is not. But petitioners also insist that – if indeed there is no jurisdiction for the DHA-PREA-FFDCA claims – then the lower courts simply had no business reaching the exhaustion issue. Clearly if petitioners had standing on the DHA-PREA-FFDCA claims, they would have had procedural standing for Count VIII to challenge FDA's exhaustion rule. Reaching the exhaustion issue necessarily – albeit implicitly – decides the disputed merits issue of the lawfulness of FDA's regulation.

Unfortunately, the need to review unlawful FDA action arises far more often than the isolated

context of this one drug. The health professionals represented by AAPS and SDW consider the need to review unlawful FDA action a critical protection of our government system. If it lacks jurisdiction, this litigation should not bar future litigation by plaintiffs with standing. Accordingly, if this Court is not inclined to take up the standing issue in this case – or if it takes this case and affirms for lack of standing – this Court should vacate the portion of the decisions below that purport to uphold FDA's regulatory exhaustion regime.

V. LOWER COURTS MUST FOLLOW PRECEDENT AND FIRST-DECIDED CASES IN INTRA-CIRCUIT SPLITS

The circuits are split on how to address intra-circuit splits, an issue that was decisive in this litigation.[10] In the criminal-justice context, this Court has recognized the "raw power of [jury] nullification." *Graham v. Collins*, 506 U.S. 461, 487 (1993) (alteration in original, interior quotation omitted) (Thomas, J., concurring). This Court's supervisory power over the lower courts requires the Court to address the judicial variety: nullification by selective application of otherwise-binding precedent.

The Ninth Circuit elevates intra-circuit splits to the *en banc* court. *Atonio v. Wards Cove Packing Co., Inc.*, 810 F.2d 1477, 1478-79 (9th Cir. 1987) (*en*

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[10] Under D.C. Circuit authority, physicians plainly have competitive standing (Section I.A.2), pharmacists plainly have informational standing (Section I.A.1), the zone of interests is either inapposite (Section I.B.3) or satisfied (Section I.B.4), and exhaustion is FDA's burden (Section II.B) and is satisfied if FDA considered petitioners' issues (Section III.A).

banc). By contrast, the weight of circuit authority (including the D.C. Circuit) calls for disregarding the second decision in the intra-circuit split, reasoning that the second three-judge panel lacked authority to overrule the decision of the initial three-judge panel. *See, e.g., Ryan v. Johnson,* 115 F.3d 193, 198 (3rd Cir. 1997); *McMellon v. United States,* 387 F.3d 329, 333 (4th Cir. 2004) (*en banc*); *Southwestern Bell Tel. Co. v. City of El Paso,* 243 F.3d 936, 940 (5th Cir. 2001); *Salmi v. Sec'y of Health & Human Servs.,* 774 F.2d 685, 689 (6th Cir. 1985); *Hiller v. Oklahoma ex rel. Used Motor Vehicle & Parts Comm'n,* 327 F.3d 1247, 1251 (10th Cir. 2003); *Morrison v. Amway Corp.,* 323 F.3d 920, 929 (11th Cir. 2003); *Indep. Cmty. Bankers of Am. v. Bd. of Govs., Fed. Reserve Sys.,* 195 F.3d 28, 34 (D.C. Cir. 1999). Finally, the Eighth Circuit takes a less disciplined approach to *stare decisis* and the authority of three-judge panels: "[w]hen there is an intra-circuit split, we are free to choose which line of cases to follow." *Toua Hong Chang v. Minnesota,* 521 F.3d 828, 832 n.3 (8th Cir. 2008).

Given the importance of *stare decisis* and judicial authority to litigants generally and to the resolution of this litigation specifically, the Court should recognize and hold that lower courts are not free to reject circuit precedent. *Stare decisis* in the lower courts is critical for the public to believe that the courts are impartial and fair.

CONCLUSION

The petition for writ of *certiorari* should be granted.

May 4, 2010

Respectfully submitted,

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United States Court of Appeals for the District of Columbia Circuit

ASS'N OF AMERICAN PHYSICIANS & SURGEONS, INC., *ET AL.*

APPELLANTS,

v.

FOOD & DRUG ADMINISTRATION, *ET AL.*,

APPELLEES.

No. 08-5458
Argued Nov. 19, 2009
Decided Nov. 27, 2009

Before: SENTELLE, Chief Circuit Judge, BROWN, Circuit Judge, and EDWARDS, Senior Circuit Judge.

JUDGMENT

This cause was considered on the record from the United States District Court for the District of Columbia, and was briefed and argued by counsel. It is

ORDERED AND ADJUDGED that the judgment of the District Court be affirmed.

In 2006, in an adjudication involving Duramed Research, Inc. (Duramed), the Food and Drug Administration ("FDA") approved a supplemental new drug application ("SNDA") filed by Duramed for Plan B, an emergency contraceptive previously available by prescription only. NDA 21-045/S-011, Letter from Steven Galson, M.D., M.P.H., Director, Center for Drug Evaluation and Research, United States Food and Drug Administration, to Joseph A.

Carrado, M.Sc., R.Ph., Vice President, Clinical Regulatory Affairs, Duramed Research, Inc. (Aug. 24, 2006), *reprinted in* Joint Appendix 77-80. The SNDA allowed Plan B to be sold over the counter to all consumers age 18 and over, while maintaining the prescription requirement for younger consumers. Appellants, Association of American Physicians & Surgeons, Inc., Concerned Women for America, Family Research Council, and Safe Drugs for Women, who were not parties to the Duramed SNDA adjudication, filed a complaint in District Court in April 2007 seeking to vacate FDA's approval of the SNDA. Appellants claimed that the FDA's action violated the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 301 *et seq.*, and the Administrative Procedure Act ("APA"), 5 U.S.C. § 706. The District Court dismissed the case for lack of standing and, in the alternative, for appellants' failure to exhaust mandatory administrative remedies. *See Ass'n of Am. Physicians & Surgeons, Inc. v. Food & Drug Admin.*, 539 F. Supp. 2d 4 (D.D.C. 2008) ("*AAPS*"). We affirm largely for the reasons stated by the District Court.

"A party invoking federal jurisdiction bears the burden of establishing standing." HARRY T. EDWARDS & LINDA A. ELLIOTT, FEDERAL STANDARDS OF REVIEW: REVIEW OF DISTRICT COURT DECISIONS AND AGENCY ACTIONS 110 (2007). *In Lujan v. Defenders of Wildlife*, 504 U.S. 555 (1992), the Court explained:

> [T]he irreducible constitutional minimum of [Article III] standing contains three elements. First, the plaintiff must have suffered an injury in fact – an invasion of a legally protected interest which is (a) concrete and particularized, and (b) actual or

> imminent, not conjectural or hypothetical. Second, there must be a causal connection between the injury and the conduct complained of – the injury has to be fairly . . .traceable to the challenged action of the defendant, and not . . . the result of the independent action of some third party not before the court. Third, it must be likely, as opposed to merely speculative, that the injury will be redressed by a favorable decision.

Id. at 560-61 (internal quotation marks and citations omitted). "In addition to determining whether a petitioner has Article III standing, a court presented with a challenge to agency action must also determine 'whether the interest sought to be protected by the complainant is arguably within the zone of interests to be protected or regulated by the statute or constitutional guarantee in question.' *Ass'n of Data Processing Serv. Orgs. v. Camp*, 397 U.S. 150, 153 (1970); see also Clarke v. Sec. Indus. Ass'n, 479 U.S. 388, 394-97 (1987). The zone-of-interest inquiry, which is 'basically one of interpreting congressional intent,' *Clarke*, 479 U.S. at 394, is a prudential requirement of general application that applies unless expressly negated by Congress. *See Bennett v. Spear*, 520 U.S. [154, 163 (1997)]." EDWARDS & ELLIOTT, supra, at 112-13. Appellants advanced numerous theories in an attempt to support their standing, but the District Court correctly found that they failed to meet their burden. *See AAPS*, 539 F. Supp. 2d at 4, 13-21. The District Court's decision needs no amplification.

Moreover, even if appellants were able to demonstrate standing, the District Court properly

found that they failed to exhaust their administrative remedies. Exhaustion applies to actions under the APA "to the extent that it is required by statute or by agency rule as a prerequisite to judicial review." *Darby v. Cisneros*, 509 U.S. 137, 147 (1993). FDA rules allow for citizen petitions through which "[a]n interested person may petition the Commissioner to issue, amend, or revoke a regulation or order, or to take or refrain from taking any other form of administrative action." 21 C.F.R. § 10.25(a). However, agency regulations explicitly require that "[a] request that the Commissioner take or refrain from taking any form of administrative action must first be the subject of a final administrative decision based on a petition submitted under § 10.25(a) or, where applicable, a hearing . . . before any legal action is filed in a court." *Id.* § 10.45(b). Appellants filed no such citizen petition with FDA contesting the SNDA approval of Plan B and they proffered no legally viable excuse for this failure.

Pursuant to D.C. Circuit Rule 36, this disposition will not be published. The Clerk is directed to withhold issuance of the mandate herein until seven days after resolution of any timely petition for rehearing or rehearing *en banc*. *See* FED. R. APP. P. 41(b); D.C. CIR. R. 41.

Per Curiam

FOR THE COURT:

Mark J. Langer, Clerk

By: /s/

Michael C. McGrail

Deputy Clerk

United States District Court for the District of Columbia

ASS'N OF AMERICAN PHYSICIANS & SURGEONS, *ET AL.*,

PLAINTIFFS,

v.

FOOD & DRUG ADMINISTRATION, *ET AL.*,

DEFENDANTS.

No. 08-5458
Argued Feb. 15, 2008
Decided Mar. 4, 2008

Before: JOHN D. BATES, District Judge.

MEMORANDUM OPINION

In August 2006, the United States Food and Drug Administration ("FDA") approved Barr Pharmaceuticals, Inc.'s ("Barr") supplemental new drug application ("SNDA") for Plan B, an emergency contraceptive drug currently marketed by Duramed Research, Inc. ("Duramed"), a wholly owned subsidiary of Barr. The approval of the SNDA allowed Plan B to be marketed without a prescription to consumers age 18 and over and retained the prescription requirement for consumers under the age of 18. Plaintiffs Association of American Physicians & Surgeons, Inc. ("AAPS"), Concerned Women for America ("CWA"), Family Research Council ("FRC"), and Safe Drugs for Women ("SDW") bring this action challenging the FDA's approval of the SNDA and the procedures the FDA employed as being in violation of the Federal Food, Drug, and Cosmetic Act ("FDCA") and the

Administrative Procedures Act ("APA"). Plaintiffs assert claims against the FDA and its Commissioner, Dr. Andrew C. von Eschenbach, in his official capacity and in his individual capacity (the "federal defendants").

Currently before the Court are motions to dismiss filed by the federal defendants and Duramed, the intervenor-defendant, pursuant to Fed.R.Civ.P. 12(b)(1) for lack of subject-matter jurisdiction and pursuant to Fed.R.Civ.P. 12(b)(6) for failure to state a claim upon which relief can be granted. Upon careful consideration of the motions, the parties' memoranda, the arguments advanced at the motions hearing held on February 15, 2008, the applicable law, and the entire record, and for the reasons set forth below, the Court will grant the federal defendants' and Duramed's motions to dismiss.

BACKGROUND

I. Statutory and Regulatory Background

Under the FDCA, a drug's sponsor must first submit a new drug application ("NDA") to the FDA for approval before a new drug may be marketed in the United States. 21 U.S.C. § 355(a)-(b). The new drug application must contain a wealth of information such as investigative reports demonstrating the drug's safety and effectiveness, a statement of the drug's components, and specimens of proposed labeling for the packaging of the new drug. *Id.* § 355(b)(1). The FDA must reject a NDA if several conditions are not met. For example, a NDA will be rejected if inadequate testing was conducted, if the testing data show that a "drug is unsafe for use under such conditions [as prescribed, recommended,

or suggested in the proposed labeling]," if there is "a lack of substantial evidence that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the proposed labeling," or if "based on a fair evaluation of all material facts, such labeling is false or misleading in any particular." *Id.* § 355(d).

Some NDAs are approved with the restriction that the drug may be dispensed by prescription only ("Rx-only"). The Rx-only requirement applies when, "because of [the drug's] toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use, [it] is not safe for use except under the supervision of a practitioner licensed by law to administer such drug." *Id.* § 353(b)(1)(A). A Rx-only drug may later be approved for over-the-counter ("OTC") use when the agency finds that the prescription requirements "are not necessary for the protection of the public health by reason of the drug's toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use, and [the agency] finds that the drug is safe and effective for use in self-medication as directed in proposed labeling." 21 C.F.R. § 310.200(b); *see also* 21 U.S.C. § 353(b)(3), 355(c)-(d).

II. Factual Background

On July 28, 1999, the FDA approved a new drug application submitted by Women's Capital Corp. ("WCC")-now a wholly owned subsidiary of Duramed-for prescription Plan B. Am. Compl. ¶ 66. In April 2003, WCC submitted a supplemental new drug application seeking to make Plan B available to all consumers over the counter in what is commonly

referred to as a Rx-to-OTC switch. *Id.* ¶ 68. Several months later, Barr acquired WCC, and thereafter Barr and Duramed continued to advocate for OTC approval of Plan B. *Id.*

After the Center for Drug Evaluation and Research ("CDER") completed its review of the application, the Acting Director issued a "not approval" letter to Duramed. *Id.* ¶ 69. The CDER cited concerns about the ability of consumers under the age of 16 to use Plan B without professional supervision by a practitioner licensed to administer the drug. *Id.* The Acting Director suggested that Duramed could: (1) provide data to demonstrate that consumers under the age of 16 could safely use Plan B as an over-the-counter drug, or (2) seek over-the-counter status solely for consumers over the age of 16. *Id.*

Duramed elected to pursue the second option and submitted an amended SNDA seeking to retain the prescription requirement for consumers under the age of 16 and seeking an OTC switch only for consumers age 16 and older. When the FDA responded on August 26, 2005, the Commissioner informed Duramed that CDER found Plan B to be safe for over-the-counter use for consumers age 17 and older. *Id.* ¶ 70. Nevertheless, the FDA did not approve this distribution scheme. Instead, the FDA indicated that it would first have to resolve whether it could approve the distribution of the same pharmaceutical drug to different populations for OTC and Rx use, and if so, how to proceed with such an approval. *Id.* ¶ 70. The FDA thereafter published an Advance Notice of Proposed Rulemaking ("ANPR") seeking public comment on these issues. *Id.* ¶ 71 (citing 70 Fed.Reg. 52,050 (Sept. 1, 2005)).

After receiving approximately 47,000 comments, the FDA determined that it was unnecessary to proceed by rulemaking. *Id.* ¶¶ 72, 74.

In August 2006, Duramed submitted yet another amended SNDA this time requesting OTC availability of Plan B for consumers age 18 and older. Fed. Defs.' Exs. 9 & 10. In its application, Duramed proposed a single package for Plan B to be used for the Rx and OTC populations. Duramed also indicated that it would only make Plan B available for purchase at licensed pharmacies and health care clinics and would direct pharmacies to keep the product "behind the counter." Fed. Defs.' Exs. 9 at 4-7 & 10 at 36-46; *see also* Am. Compl. ¶ 78. In August 2006, the FDA approved this amended SNDA. Am. Compl. ¶ 78. As approved by the FDA, Plan B's current labeling contains the legend "Rx only for age 17 and younger." *Id.* ¶ 79.

III. Procedural Background

Almost eight months later, on April 12, 2007, plaintiffs AAPS, CWA, FRC and SDW filed this action seeking to vacate the FDA's August 2006 SNDA approval decision for Plan B. Plaintiff AAPS is a not-for-profit membership organization of physicians who practice in all areas and specialities. *Id.* ¶ 3. Plaintiff CWA is a nonprofit corporation that represents approximately 500,000 men and women across the nation advancing their interests before Congress and other governmental bodies. *Id.* ¶ 4. Plaintiff FRC is a nonprofit corporation dedicated to "valuing human life from conception until natural death and upholding the institution of the family, including parental oversight of children's health care." *Id.* ¶ 5. And Plaintiff SDW is a nonprofit

corporation whose members consist of physicians and pharmacists. *Id.* ¶ 6.

After the federal defendants and Duramed filed motions to dismiss arguing that plaintiffs lacked standing to sue, plaintiffs filed an amended complaint in an attempt to cure any pleading deficiencies. In their amended complaint, plaintiffs allege: (1) that the FDA's approval was unlawful because the SNDA failed to demonstrate that Plan B was safe for OTC use by consumers age 18 and older, (2) that the FDA's approval violated the FDCA by allowing Plan B to be marketed as both a prescription and an OTC drug, (3) that the FDA's age-based decision violated the FDCA, (4) that the FDA has created a "third class" of drugs in violation of the FDCA, (5) that the FDA violated the APA by failing to conduct a rulemaking, (6) that the FDA violated the FDCA by failing to conduct a rulemaking, (7) that the federal defendants were improperly influenced by political pressure, and (8) that the FDA is not authorized to impose administrative exhaustion requirements.

In response to the amended complaint, the federal defendants and Duramed (collectively the defendants) again filed motions to dismiss arguing that plaintiffs' allegations are insufficient to establish the elements of standing and that plaintiffs have failed to exhaust their administrative remedies. Defendants also argue that plaintiffs' theories underlying Counts II, IV, V, and VI are incorrect as a matter of law. Finding the jurisdictional argument of defendants persuasive, the Court will grant the motions to dismiss.

STANDARD OF REVIEW

"[I]n passing on a motion to dismiss, whether on the ground of lack of jurisdiction over the subject matter or for failure to state a cause of action, the allegations of the complaint should be construed favorably to the pleader." *Scheuer v. Rhodes*, 416 U.S. 232, 236, 94 S.Ct. 1683, 40 L.Ed.2d 90 (1974); *see Leatherman v. Tarrant Cty. Narcotics and Coordination Unit*, 507 U.S. 163, 164, 113 S.Ct. 1160, 122 L.Ed.2d 517 (1993); *Phillips v. Bureau of Prisons*, 591 F.2d 966, 968 (D.C.Cir.1979). Therefore, the factual allegations must be presumed true, and plaintiff must be given every favorable inference that may be drawn from the allegations of fact. *Scheuer*, 416 U.S. at 236, 94 S.Ct. 1683; *Sparrow v. United Air Lines, Inc.*, 216 F.3d 1111, 1113 (D.C.Cir.2000). However, the Court need not accept as true "a legal conclusion couched as a factual allegation," nor inferences that are unsupported by the facts set out in the complaint. *Trudeau v. Federal Trade Comm'n*, 456 F.3d 178, 193 (D.C.Cir.2006) (quoting *Papasan v. Allain*, 478 U.S. 265, 286, 106 S.Ct. 2932, 92 L.Ed.2d 209 (1986)).

Under Rule 12(b)(1), the parties seeking to invoke the jurisdiction of a federal court-plaintiffs here-bear the burden of establishing that the court has jurisdiction. *See U.S. Ecology, Inc. v. U.S. Dep't of Interior*, 231 F.3d 20, 24 (D.C.Cir.2000); *see also Grand Lodge of Fraternal Order of Police v. Ashcroft*, 185 F.Supp.2d 9, 13 (D.D.C.2001) (a court has an "affirmative obligation to ensure that it is acting within the scope of its jurisdictional authority."); *Pitney Bowes, Inc. v. United States Postal Serv.*, 27 F.Supp.2d 15, 19 (D.D.C.1998). " '[P]laintiff's factual

allegations in the complaint ... will bear closer scrutiny in resolving a 12(b)(1) motion' than in resolving a 12(b)(6) motion for failure to state a claim." *Grand Lodge,* 185 F.Supp.2d at 13-14 (quoting 5A Charles A. Wright & Arthur R. Miller, Federal Practice and Procedure § 1350 (2d ed.1987)). Additionally, a court may consider material other than the allegations of the complaint in determining whether it has jurisdiction to hear the case, as long as it still accepts the factual allegations in the complaint as true. *See Jerome Stevens Pharmaceuticals, Inc. v. FDA,* 402 F.3d 1249, 1253-54 (D.C.Cir.2005); *EEOC v. St. Francis Xavier Parochial Sch.,* 117 F.3d 621, 624-25 n. 3 (D.C.Cir.1997); *Herbert v. Nat'l Acad. of Scis.,* 974 F.2d 192, 197 (D.C.Cir.1992).

In reviewing a motion to dismiss pursuant to Rule 12(b)(6), the Court is mindful that all that the Federal Rules of Civil Procedure require of a complaint is that it contain " 'a short and plain statement of the claim showing that the pleader is entitled to relief,' in order to 'give the defendant fair notice of what the ... claim is and the grounds upon which it rests.' " *Bell Atl. Corp. v. Twombly,* 550 U.S. ----, 127 S.Ct. 1955, 1964, 167 L.Ed.2d 929 (2007) (quoting *Conley v. Gibson,* 355 U.S. 41, 47, 78 S.Ct. 99, 2 L.Ed.2d 80 (1957)); *accord Erickson v. Pardus,* 551 U.S. ----, 127 S.Ct. 2197, 2200, 167 L.Ed.2d 1081 (2007) (per curiam). "A Rule 12(b)(6) motion tests the legal sufficiency of a complaint." *Browning v. Clinton,* 292 F.3d 235, 242 (D.C.Cir.2002). Thus, the complaint's "[f]actual allegations must be enough to raise a right to relief above the speculative level, on the assumption that all the allegations in the complaint are true (even if doubtful in fact)." *Bell Atl.*

Corp., 127 S.Ct. at 1965 (citations omitted).

DISCUSSION

The defendants' motions raise threshold justiciability issues before specifically addressing Counts II, IV, V, and VI of the amended complaint. A matter may be rendered nonjusticiable for a variety of reasons, frequently blending constitutional and prudential considerations. *See Flast v. Cohen,* 392 U.S. 83, 95, 88 S.Ct. 1942, 20 L.Ed.2d 947 (1968) ("no justiciable controversy is presented ... when the question sought to be adjudicated has been mooted by subsequent developments, and when there is no standing to maintain the action"). In this case, the absence of standing deprives this Court of jurisdiction to grant the relief plaintiffs request, and the failure to exhaust administrative remedies further renders the action nonjusticiable.

I. Standing

The authority of the judiciary is limited by Article III of the Constitution to the "resolution of 'cases' and 'controversies.' " *Valley Forge Christian College v. Americans United for Separation of Church and State, Inc.*, 454 U.S. 464, 471, 102 S.Ct. 752, 70 L.Ed.2d 700 (1982). This principle of limited judicial authority is, in part, manifest by the requirement that a litigant must have standing to bring an action, and thus be "entitled to have the court decide the merits of the dispute or of particular issues." *Warth v. Seldin,* 422 U.S. 490, 498, 95 S.Ct. 2197, 45 L.Ed.2d 343 (1975). The standing inquiry asks "whether the plaintiff has 'alleged such a personal stake in the outcome of the controversy' as to warrant his invocation of federal-court jurisdiction and to justify exercise of the court's remedial powers

on his behalf." *Id.* (quoting *Baker v. Carr*, 369 U.S. 186, 204, 82 S.Ct. 691, 7 L.Ed.2d 663 (1962)).

Standing is a requirement, therefore, that every litigant-whether an individual or an organization-in a federal lawsuit must satisfy. It is a burden borne by the plaintiff and each element of standing "must be supported in the same way as any other matter on which the plaintiff bears the burden of proof, i.e., with the manner and degree of evidence required at the successive stages of the litigation." *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 561, 112 S.Ct. 2130, 119 L.Ed.2d 351 (1992). At a minimum, a plaintiff must establish three elements: (1) that he "suffered an 'injury in fact'-an invasion of a legally protected interest which is (a) concrete and particularized ... and (b) actual or imminent, not 'conjectural' or 'hypothetical' ...," (2) "there must be a causal connection between the injury and the conduct complained of," and (3) "it must be likely, as opposed to merely speculative, that the injury will be redressed by a favorable decision." *Id.* at 560, 112 S.Ct. 2130 (citations and quotations omitted).

Furthermore, to challenge agency action, plaintiffs must satisfy the additional requirement of prudential standing. Litigants have prudential standing to sue if they fall within the zone of interests protected or regulated by the statute at issue, here the FDCA. *See Bennett v. Spear*, 520 U.S. 154, 162, 117 S.Ct. 1154, 137 L.Ed.2d 281 (1997). The zone-of-interests test is not, however, meant to be especially onerous. Rather, it "is intended to 'exclude only those whose interests are so marginally related to or inconsistent with the purposes implicit in the statute that it cannot reasonably be assumed that Congress intended to permit the suit.' " *Nat'l*

Ass'n of Home Builders v. United States Army Corps of Eng'rs, 417 F.3d 1272, 1287 (D.C.Cir.2005) (quoting *Clarke v. Sec. Indus. Ass'n*, 479 U.S. 388, 399, 107 S.Ct. 750, 93 L.Ed.2d 757 (1987)).

As plaintiffs here are all organizations, they may assert standing in their own capacity by satisfying the above requirements. Additionally, an organization may establish representational standing if: (1) at least one of its members has standing to sue in his or her own right; (2) the interests the association seeks to protect are germane to its purpose, and (3) neither the claim asserted nor the relief requested requires the participation of an individual member in the lawsuit. *American Library Ass'n v. FCC*, 401 F.3d 489, 492 (D.C.Cir.2005); *see also Hunt v. Washington State Apple Adver. Comm'n*, 432 U.S. 333, 343, 97 S.Ct. 2434, 53 L.Ed.2d 383 (1977).

In their amended complaint, plaintiffs seek to establish representational standing based upon six alleged injuries that flow from the FDA's approval of the August 2006 SNDA. First, plaintiffs argue that their members were deprived of their FDCA-granted right to information. Am. Compl. ¶ 17. Second, they argue that consumers age 18 and older are now subject to an increased risk of harm from foregoing doctor visits, which are no longer necessary to obtain Plan B. *Id.* ¶ 18. Third, plaintiffs assert that their member physicians now "face increased competition from pharmacists ... in the contraceptive area of their medical practice" and that physicians will lose money from lost office visits since consumers age 18 and older can now obtain Plan B OTC. *Id.* ¶¶ 19-20. Fourth, plaintiffs contend that their member physicians have third-party standing to assert the

rights of their patients. *Id.* ¶¶ 21-22. Fifth, they assert that the FDA's approval of the SNDA subjects their member pharmacists to an increased risk of liability, additional administrative burdens, and compelled speech in violation of conscience-based objections. *Id.* ¶¶ 23-26. And sixth, plaintiffs assert-on their own behalf and on behalf of their members-that the FDA's failure to engage in rulemakings deprived them of procedures to which they were entitled. *Id.* ¶ 27.

Defendants challenge plaintiffs' ability to satisfy all three requirements for constitutional standing. They argue that plaintiffs' injuries are not concrete and particularized, and actual or imminent. Rather, defendants contend that plaintiffs' injuries are hypothetical and based upon speculation. To support their argument defendants correctly point out that plaintiffs fail to allege that using Plan B causes harm directly and fail to identify a single individual who has been harmed by Plan B's OTC availability. Defendants also argue that the alleged injuries are not fairly traceable to the FDA's approval decision. Instead, defendants assert that plaintiffs base their standing on purely conjectural claims caused by the independent decisions and actions of third parties. Defendants further contend that plaintiffs are not seeking an appropriate remedy that would redress their alleged injuries. And finally, defendants argue that the FDCA does not grant plaintiffs a right to information to support informational standing.

"For each claim, if constitutional and prudential standing can be shown for at least one plaintiff, [the court] need not consider the standing of the other plaintiffs to raise that claim." *Mountain States Legal Foundation v. Glickman*, 92 F.3d 1228, 1232

(D.C.Cir.1996) (citing *Watt v. Energy Action Educational Foundation*, 454 U.S. 151, 160, 102 S.Ct. 205, 70 L.Ed.2d 309 (1981)); *Village of Arlington Heights v. Metro. Housing Devel. Corp.*, 429 U.S. 252, 264 n. 9, 97 S.Ct. 555, 50 L.Ed.2d 450 (1977). Relying on this precedent at the motions hearing, plaintiffs' counsel indicated that plaintiffs were no longer putting forward standing claims for CWA and FRC and would instead base their standing upon AAPS and SDW suing on behalf of physicians and pharmacists.[1]XXX *See* Preliminary

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[1] Plaintiffs' decision was motivated by recent D.C. Circuit authority, *see Public Citizen, Inc. v. National Highway Traffic Safety Admin.* ("*NHTSA II*"), 513 F.3d 234 (D.C.Cir.2008), and *Public Citizen, Inc. v. National Highway Traffic Safety Admin.* ("*NHTSA I*"), 489 F.3d 1279 (D.C.Cir.2007), and this Court's inquiry as to whether CWA and FRC are membership organizations. In at least two cases, the D.C. Circuit has determined that organizations lacked standing for failing to satisfy this requirement. *See Fund Democracy, LLC v. SEC*, 278 F.3d 21, 25-26 (D.C.Cir.2002) (no standing for one-person business purporting to represent tens of millions of individual investors, where there was no evidence of any alleged supporter who funded or approved of organization's activities); *Am. Legal Found. v. FCC*, 808 F.2d 84, 90 (D.C.Cir.1987) (no standing for organization that did not represent a "discrete, stable group of persons with a definable set of common interests" and organization's supporters did not appear to play any role in selecting its leadership or guiding or funding its activities). "In determining whether an organization that has no members in the traditional sense may nonetheless assert associational standing, the question is whether the organization is the functional equivalent of a traditional membership organization." *Fund Democracy, LLC*, 278 F.3d at 25. Neither the amended complaint nor the opposition are very forthcoming with information to aid the Court in this analysis.

Furthermore, the amended complaint fails to allege any organizational purpose for CWA. To establish representational

Tr., Feb. 15, 2008, at 46-48, 70-71. In response, defendants further contend that physicians and pharmacists lack prudential standing because their alleged grievances do not fall within the zone of interests protected by the FDCA.[2]

A. Informational Injury

"Informational standing arises 'only in very specific statutory contexts' where a statutory provision has 'explicitly created a right to information.' " *American Farm Bureau v. EPA*, 121 F.Supp.2d 84, 97 (D.D.C.2000) (quoting *Animal Legal Defense Fund, Inc. v. Espy*, 23 F.3d 496, 502 (D.C.Cir.1994)). For example, in *Havens Realty Corp.*

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standing, an organization must allege that the interests it seeks to protect through the litigation are germane to its purpose. Although the germaneness prong is undemanding, only requiring "that an organization's litigation goals be pertinent to its special expertise and the grounds that bring its membership together," CWA may also not meet this requirement based upon its complete failure to explain what grounds bring its membership together-if indeed it has members. *Humane Soc. of the U.S. v. Hodel*, 840 F.2d 45, 56 (D.C.Cir.1988).

[2] Plaintiffs submitted a notice of supplemental authority on February 12, 2008, attaching an unpublished opinion in *Ass'n of Am. Physicians & Surgeons v. FDA*, No. 00-2898 (D.D.C.2001), where the court determined that AAPS had standing to challenge the FDA's regulations regarding pediatric testing of new drugs. In the notice, plaintiffs argued that AAPS must necessarily have standing in the instant action based upon mutual collateral estoppel. At the motions hearing, however, plaintiffs appeared to concede that this was an erroneous assertion. *See* Preliminary Tr., Feb. 15, 2008, at 51. Plaintiffs' interpretation of the collateral estoppel doctrine would allow AAPS to sue the FDA in any situation merely because one district court previously determined that AAPS had standing in a single case.

v. Coleman, 455 U.S. 363, 373, 102 S.Ct. 1114, 71 L.Ed.2d 214 (1982), the Supreme Court determined that the combination of two provisions of the Fair Housing Act of 1968 supported informational standing. First, the Act made it unlawful for entities "[t]o represent to any person because of race, color, religion, sex, or national origin that any dwelling is not available for inspection, sale, or rental when such dwelling is in fact so available, 42 U.S.C. § 3604(d)." *Id.* at 373, 102 S.Ct. 1114. And second, this prohibition was made enforceable through an explicit cause of action in § 812(a) of the Act, 42 U.S.C. § 3612(a). *Id.* Based upon these provisions, Congress had "thus conferred on all 'persons' a legal right to truthful information about available housing." *Id.*

The statutory framework here is unlike the one at issue in *Havens Realty*. Plaintiffs cannot demonstrate that Congress intended to confer upon them a legal right to the information they seek. Moreover, plaintiffs cite no authority for the proposition that the FDCA can support informational standing. Defendants, on the other hand, point to *American Farm Bureau v. EPA*, 121 F.Supp.2d 84 (D.D.C.2000) , in which the court rejected the plaintiff's informational standing theory under the FDCA. Although the court was addressing a provision that is not cited by plaintiffs here, that court clearly stated that the "FFDCA does not confer a broad, legally enforceable right to information." *Id.* at 99.

Plaintiffs' theory is overly expansive and unsupported by the case law they cite. *Public Citizen v. FTC*, 869 F.2d 1541, 1543 (D.C.Cir.1989), is the most helpful case for plaintiffs, but it too is distinguishable. There, the Smokeless Tobacco Act

provided that: "It shall be unlawful for any manufacturer ... of smokeless tobacco products to advertise or cause to be advertised (other than through the use of outdoor billboard advertising) within the United States any smokeless tobacco product unless the advertising bears, in accordance with the requirements of this chapter, one of the labels required by paragraph (1)." *Id.* at 1543 (quoting 15 U.S.C. § 4402(a)(2)). The FTC then promulgated a regulation that exempted "utilitarian objects for personal use" from the warning requirement. *Id.* at 1544. Because the statute required warnings on all forms of advertising other than outdoor billboards, the court determined that plaintiffs had standing to challenge the deprivation "of valuable warnings to which Congress allegedly determined they were entitled." *Id.* at 1547.

In focusing on the plaintiffs' injuries in *Public Citizen*, the D.C. Circuit noted that the injury "resides not in what might be called the 'speculative' chance that members will in fact become snuffdippers, or that their health will suffer as a result; rather, it arises from the more *certain* charge that they are being deprived of information and warnings that will be of substantial value to them and to which they are legally entitled." *Id.* at 1546. Here, in contrast, plaintiffs do not put forth sufficient factual allegations to indicate that they have been deprived of information to which they are legally entitled. Instead, plaintiffs focus on the more speculative chance that their members may be misled based upon the efficacy information that is

contained on Plan B's labeling.[3]

Moreover, even if plaintiffs were able to establish that the FDCA could support informational standing and that their members had suffered a concrete and particularized injury, plaintiffs would still fail to satisfy the redressability prong for constitutional standing. In *Public Citizen,* the court noted that the plaintiffs' injury regarding the deprivation of warnings would be redressed by a favorable court decision because a successful challenge would "result in the FTC *requiring* the inclusion of warnings on utilitarian items." *Id.* at 1547. Here, plaintiffs have not demonstrated that the remedy they seek would likely redress the labeling deficiencies they allege regarding Plan B. If the SNDA is vacated, Plan B would remain available by prescription, with presumably the same information on the label regarding its efficacy. It would simply no longer be available OTC. As defendants point out, the FDA provides an avenue for plaintiffs to achieve the

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[3] At the motions hearing on February 15, 2008, plaintiffs vaguely indicated that they could establish informational standing based upon recent amendments to the Pediatric Research Equity Act. Plaintiffs' amended complaint, however, asserts no claims based upon these amendments, and plaintiffs failed to raise this argument in their opposition or in their two supplemental filings. Furthermore, plaintiffs did not point the Court to any specific provision that would support their contention. Upon the Court's review of 21 U.S.C. § 355c, it appears that the amendments apply to drug applications submitted on or after September 27, 2007, and to already approved applications if the Secretary so orders in his discretion. Here, Duramed's SNDA was submitted more than a year before these amendments took effect, and there is no allegation that the Secretary has ordered Duramed to submit such assessments for its already approved application.

labeling changes they desire. Plaintiffs may file a citizen petition under 21 C.F.R. §§ 10.25, 10.30. The Court therefore concludes that plaintiffs' alleged informational injuries are inadequate to support constitutional standing here.

B. Increased Risk of Harm

In their amended complaint, plaintiffs argue that the FDA's approval of the SNDA will lead to an increased risk of harm for consumers of Plan B who are age 18 and older. According to plaintiffs, these consumers "will fail to receive critical health-care protection as the result of foregoing doctor visits previously required for contraceptives." Am. Compl. ¶ 18. Although the D.C. Circuit "has not closed the door to all increased-risk-of-harm cases," the door remains only slightly ajar. *NHTSA II,* 513 F.3d 234, 237-38 (quoting *NHTSA I,* 489 F.3d at 1295). In such cases, the D.C. Circuit has only "allowed standing when there was at least *both* (i) a *substantially* increased risk of harm and (ii) a *substantial* probability of harm with that increase taken into account." *Id.* (quoting *NHTSA I,* 489 F.3d at 1295, and citing *Natural Resources Defense Council v. EPA,* 464 F.3d 1, 6-7 (D.C.Cir.2006), and *Mountain States Legal Found.,* 92 F.3d at 1234-35). In applying this standard, the courts keep in mind that " 'the constitutional requirement of imminence as articulated by the Supreme Court' requires 'a very strict understanding of what increases in risk and overall risk levels' will support injury in fact." *Id.* at 240-41 (quoting *NHTSA I,* 489 F.3d at 1296). Based upon these D.C. Circuit precedents, plaintiffs have now conceded that they have not demonstrated sufficient injury in fact to support their public safety

standing argument. *See* Preliminary Tr., Feb. 15, 2008, at 46-48, 70-71.

C. Physicians' Competitive and Economic Injuries

Plaintiffs allege that their member physicians will now suffer competitive and economic injuries because "[b]oth existing patients and new patients who otherwise would have come to such physicians to obtain a contraceptive prescription instead now can obtain Plan B directly from pharmacists, without first visiting a physician's office to obtain a prescription." Am. Compl. ¶ 20. Plaintiffs allege that physicians will lose the non-nominal financial benefit from these office visits.

Although Plan B was available OTC for one full year before plaintiffs filed their amended complaint, they fail to allege that any physician has in fact suffered a loss of revenue in this manner. The declaration attached to plaintiffs' opposition also fails to allege any concrete injury in fact. Instead, plaintiffs' claims are purely hypothetical and speculative. Moreover, plaintiffs have not demonstrated that such alleged injuries would be causally connected to the FDA's approval of the SNDA. Causation is substantially more difficult to prove when it "depends on the unfettered choices made by independent actors not before the courts and whose exercise of broad and legitimate discretion the courts cannot presume either to control or to predict." *Lujan*, 504 U.S. at 562, 112 S.Ct. 2130 (quoting *ASARCO Inc. v. Kadish*, 490 U.S. 605, 615, 109 S.Ct. 2037, 104 L.Ed.2d 696 (1989)). Here, any loss of revenue suffered by physicians would be attributable to the independent choices of women to

forego office visits. Nothing in the FDA's approval of the SNDA forbids a woman from first consulting with her doctor before obtaining Plan B, even if it is sold OTC.

In any event, plaintiffs cannot prevail with this standing argument because their alleged competitive and economic injuries do not fall within the zone of interests of the FDCA for prudential standing. The zone-of-interests test excludes "those whose interests are so marginally related to or inconsistent with the purposes implicit in the statute that it cannot reasonably be assumed that Congress intended to permit the suit.'" *Nat'l Ass'n of Home Builders,* 417 F.3d at 1287 (quoting *Clarke v. Sec. Indus. Ass'n,* 479 U.S. 388, 399, 107 S.Ct. 750, 93 L.Ed.2d 757 (1987)). The relevant zone of interests is determined "not by reference to the overall purpose of the Act in question ..., but by reference to the particular provision" at issue in the litigation. *Grand Council of Crees (of Quebec) v. FERC,* 198 F.3d 950, 956 (D.C.Cir.2000) (quoting *Bennett,* 520 U.S. at 175-76, 117 S.Ct. 1154).

Here, this litigation revolves around the Rx-to-OTC provisions of the FDCA. In enacting these provisions, Congress had "a two-fold objective: (1) to protect the public from abuses in the sale of potent prescription drugs; and (2) to relieve retail pharmacists and the public from burdensome and unnecessary restrictions on the dispensing of drugs that are safe for use without the supervision of a physician." Sen. Report No. 82-946 (1951), 1951 U.S.C.C.A.N. 2454, 2454. Noticeably absent from these objectives is any intent to increase or maintain the revenue physicians generate from office visits when patients seek prescription drugs. In fact, as

defendants note, physicians' "alleged interest in generating fees from unnecessary doctor visits is antithetical to the purposes of the FDCA." Fed. Defs.' Mem. at 15. These provisions were enacted to provide consumers with easier access to drugs that do not first require consultation with a physician, not to maintain the constraints on access inherent in requiring physician visits. Thus, physicians lack prudential standing under the FDCA.[4]

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[4] Plaintiffs argue that even if they are not intended beneficiaries within the zone of interests they are at least suitable challengers. Courts may deem certain parties to be suitable challengers "if their interests are sufficiently congruent with those of the intended beneficiaries [such] that the litigants are not 'more likely to frustrate than to further the statutory objectives.' " *First Nat. Bank and Trust Co. v. National Credit Union Admin.*, 988 F.2d 1272, 1275 (D.C.Cir.1993) (quoting *Clarke v. Sec. Indus. Ass'n*, 479 U.S. at 397, 107 S.Ct. 750). As discussed above, however, it is evident that the asserted interest of physicians to increase their revenue from office visits is incongruent with the interests of consumers to obtain drugs that are safe for over-the-counter use without unnecessary expenses.

Plaintiffs' argument that they may evade the prudential standing analysis altogether by labeling the FDA's approval of the SNDA *ultra vires* is equally unavailing. "[A]n *ultra vires* claim rests on 'the officer's lack of delegated power. A claim of error in the exercise of that power is therefore not sufficient.' " *Pennhurst State School & Hosp. v. Halderman*, 465 U.S. 89, 102, 104 S.Ct. 900, 79 L.Ed.2d 67 (1984) (quoting *Larson v. Domestic & Foreign Commerce Corp.*, 337 U.S. 682, 690, 69 S.Ct. 1457, 93 L.Ed. 1628 (1949)). Here, it is undisputed that the FDA has the authority to approve Rx-to-OTC switches. Plaintiffs simply argue that the FDA made substantive and procedural errors in approving the SNDA for the Rx-to-OTC switch of Plan B. In any event, plaintiffs have failed to satisfy the Article III requirements for standing, so the prudential analysis is not outcome determinative.

D. Physicians' Third-Party Standing on Behalf of their Patients

A "plaintiff generally must assert his own legal rights and interests, and cannot rest his claim to relief on the legal rights or interests of third parties." *Warth,* 422 U.S. at 499, 95 S.Ct. 2197. Despite this general prohibition, plaintiffs AAPS and SDW allege that their physician members have third-party standing to sue on behalf of their patients. To establish third-party standing, a litigant must satisfy three requirements: "The litigant must have suffered an 'injury in fact,' thus giving him or her a 'sufficiently concrete interest' in the outcome of the issue in dispute; the litigant must have a close relation to the third party; and there must exist some hindrance to the third party's ability to protect his or her own interests." *Powers v. Ohio,* 499 U.S. 400, 411, 111 S.Ct. 1364, 113 L.Ed.2d 411 (1991) (citing *Singleton v. Wulff,* 428 U.S. 106, 96 S.Ct. 2868, 49 L.Ed.2d 826 (1976)) (internal citations omitted).

As discussed above, neither AAPS, SDW, nor their members have alleged a redressable concrete injury sufficient to establish standing on their own behalf. Hence, plaintiffs cannot rely on the legal rights and interests of potential or current patients to substitute for their own lack of standing. Additionally, plaintiffs have not established that a genuine hindrance prevents patients from protecting their own interests. In fact, some consumers were already before this Court in this lawsuit since CWA alleged representational standing on behalf of "women and parents of girls who would consider taking (or having their minor girl take) Plan B." Am.

Compl. ¶ 15. In any event, plaintiffs' allegations indicate that the alleged rights of their patients may not truly be at stake because, according to plaintiffs, even if patients "recognize Plan B's various limitations, their typical response is simply to refrain prospectively from purchasing Plan B or relying on its label information." *Id.* ¶ 22. Plaintiffs' concession further undermines their argument that a genuine obstacle is preventing patients from asserting their own rights. For these reasons, plaintiffs have not established third-party standing based on their member physicians' patients.

E. Pharmacists' Injuries

Plaintiffs assert that the FDA's approval of the SNDA subjects their member pharmacists to an increased risk of liability, additional administrative burdens, and compelled speech in violation of conscience-based objections. Am. Compl. ¶¶ 23-26. As to the claims of increased risk of liability, plaintiffs assert that their member pharmacists: (1) may be prosecuted for selling a misbranded drug and (2) may face "expanded legal liability from the removal of the otherwise-applicable protections afforded to pharmacists who dispense an Rx drug pursuant to a physician's prescription." *Id.* ¶¶ 23-24. Plaintiffs' allegations are purely speculative, however. No pharmacist has alleged that he has been prosecuted or subjected to liability in either manner.

Indeed, it is a stretch to say that a pharmacist could be prosecuted for selling a misbranded drug when there has been no determination that Plan B is misbranded. "When plaintiffs 'do not claim that they have ever been threatened with prosecution, that a prosecution is likely, or even that a prosecution is

remotely possible,' they do not allege a dispute susceptible to resolution by a federal court." *Babbitt v. United Farm Workers Nat. Union,* 442 U.S. 289, 299, 99 S.Ct. 2301, 60 L.Ed.2d 895 (1979) (quoting *Younger v. Harris,* 401 U.S. 37, 42, 91 S.Ct. 746, 27 L.Ed.2d 669 (1971)). Because the pharmacists' fears of prosecution here "are imaginary or speculative, [they] are not to be accepted as appropriate plaintiffs.' " *Babbitt,* 442 U.S. at 298, 99 S.Ct. 2301 (quoting *Younger,* 401 U.S. at 42, 91 S.Ct. 746).

Plaintiffs' second argument regarding an increased risk of liability fares no better. They explain that pharmacists are often immune from malpractice suits when they correctly fill a physician's prescription. Pls.' Opp. at 11. But while Plan B is now available OTC for consumers age 18 and older, that does not prevent pharmacists from correctly dispensing Plan B to limit their exposure to any form of legal liability. Again, no facts to support an assertion of increased risk have been presented by plaintiffs. Their claim that their risk of legal liability has increased, then, is speculative and lacking in any causal connection to the FDA's approval of the SNDA.

Plaintiffs next allege that pharmacists face added administrative burdens in OTC dispensing of Plan B. Neither the amended complaint, the opposition, nor the exhibits, however, specify what these alleged administrative burdens are. Although the manner and degree of evidence required to support the elements of standing vary at the successive stages of litigation, on a motion to dismiss a plaintiff must still provide sufficient factual allegations to support the alleged injury. *Lujan,* 504 U.S. at 561, 112 S.Ct. 2130. Here, plaintiffs'

pleadings are devoid of such factual allegations. Logically, it seems as though the administrative burdens of pharmacists would have decreased after the FDA approved the SNDA. To sell Plan B over the counter to the correct age population, a clerk would have to check a consumer's identification. Prior to the SNDA, when Plan B was prescription only, pharmacists would presumably have to receive, verify, file, and maintain all consumers' prescriptions.

Finally, the Court need not linger long on plaintiffs' compelled speech argument. The FDA's approval of the SNDA does not force or require any pharmacist to sell Plan B-whether or not he or she has conscience-based objections to the drug itself. Moreover, pharmacists dispense Plan B whether by Rx or OTC, and hence approval of the SNDA has not really impacted their speech. Thus, plaintiffs cannot show that this alleged injury is fairly traceable to the challenged action of the defendants.

F. Procedural Injury

Plaintiffs assert procedural injury on their own behalf and on behalf of their members as their last basis for standing. "The mere violation of a procedural requirement [however] does not permit any and all persons to sue to enforce the requirement." *Florida Audubon Soc. v. Bentsen*, 94 F.3d 658, 664 (D.C.Cir.1996). The D.C. Circuit has held that, to demonstrate injury sufficient for standing in a procedural rights case, the plaintiff must show that the omission or insufficiency of the procedure has "demonstrably increased [the] risk of serious ... harm" that "actually threatens the plaintiff's particular interests." *Id.* at 667; *see also*

Commonwealth of Massachusetts v. EPA, 415 F.3d 50, 60 (D.C.Cir.2005) (Sentelle, J., concurring) (applying "demonstrably increased risk" standard in cases outside of NEPA). A plaintiff may not establish standing based on a procedural injury unless the plaintiff alleges that the procedural violation "has resulted in an invasion of their concrete and particularized interest." *Center for Law and Educ. v. Department of Educ.*, 396 F.3d 1152, 1159 (D.C.Cir.2005). Moreover, on the causation prong, "a procedural-rights plaintiff must show ... that it is substantially probable that the procedural breach will cause the essential injury to the plaintiff's own interest." *Florida Audubon Soc'y*, 94 F.3d at 664-65. Thus, "the primary focus of the standing inquiry is not the imminence or redressability of the injury to the plaintiff, but whether a plaintiff who has suffered personal and particularized injury has sued a defendant who has caused that injury." *Id.* at 664.

Here, plaintiffs argue that they were denied the opportunity to participate in notice and comment rulemakings for the Rx-to-OTC switch for Plan B. Plaintiffs have not, however, identified a legally protected interest that has been infringed by these alleged procedural shortcomings. Plaintiffs advance no allegations of injury suffered by the organizations themselves, and as explained above, plaintiffs have not demonstrated a concrete injury in relation to their members. Moreover, the Supreme Court "has never freed a plaintiff alleging a procedural violation from showing a causal connection between the government action that supposedly required the disregarded procedure and some reasonably increased risk of injury to its particularized interest," and here, plaintiffs have not demonstrated a

sufficient causal connection between a procedural violation and an alleged injury. *Id.; California Forestry Assoc. v. Thomas,* 936 F.Supp. 13, 19-20 (D.D.C.1996). The allegations in plaintiffs' amended complaint, then, are insufficient to support procedural standing.

II. Exhaustion

Plaintiffs have failed to establish standing because they lack a sufficient personal stake in the outcome of the litigation so as to warrant the invocation of federal-court jurisdiction. Nonetheless, defendants present a second argument for the dismissal of the amended complaint, namely plaintiffs' failure to exhaust their administrative remedies. This threshold issue presents a more difficult question, but the Court ultimately finds defendants' argument persuasive.

It is undisputed that the FDA's approval of a SNDA is a relatively closed process. The FDA does however provide an opportunity for interested parties, such as plaintiffs, to participate in the regulatory process through the submission of a citizen petition. *See* 21 C.F.R. § 10.25(a) (providing that "[a]n interested person may petition the Commissioner to issue, amend, or revoke a regulation or order, or to take or refrain from taking any other form of administrative action"); *see also* 21 C.F.R. § 10.30. In fact, the FDA's regulations under the FDCA *require* that a request that the "Commissioner take or refrain from taking any form of administrative action must first be the subject of a final administrative decision based on a petition submitted under § 10.25(a) ... before any legal action is filed in a court complaining of the action or failure

to act." *Id.* § 10.45(b). Although plaintiffs claim to have submitted comments during the agency's general ANPR, they in no way participated in the SNDA approval process for Plan B.[5] Thus, the agency was never provided with an opportunity to address plaintiffs' requests that the FDA take certain actions, such as amending the labeling of Plan B.

Nevertheless, plaintiffs present two arguments to support their contention that the amended complaint should not be dismissed for failure to exhaust administrative remedies. First, plaintiffs rely on *Darby v. Cisneros*, 509 U.S. 137, 147, 113 S.Ct. 2539, 125 L.Ed.2d 113 (1993), in which the Supreme Court held that federal courts cannot require plaintiffs seeking judicial review under the APA to exhaust *optional* administrative remedies. The administrative remedy here is mandated by regulation, however, and *Darby* explicitly stated that "the exhaustion doctrine continues to exist under the APA to the extent that it is required by statute or by *agency rule* as a prerequisite to judicial review." *Id.* at 153, 113 S.Ct. 2539 (emphasis added).

Plaintiffs' second argument is more appealing,

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[5] To the extent that plaintiffs are now arguing that their participation in the ANPR process satisfied FDA exhaustion requirements, the Court has no evidence to support this contention. Plaintiffs failed to attach any such evidence to their opposition, failed to present any such evidence at the motions hearing, and failed to submit any such evidence after the motions hearing despite two supplemental notices, which indicated plaintiffs' intent to do so. Because plaintiffs were on notice of defendants' exhaustion argument and had ample time to oppose the motions to dismiss, the Court will take the record as it currently stands.

yet it cannot stand when the regulations are read in context together. Plaintiffs rely on 21 C.F.R. § 10.45(e) divorced from the FDA's other regulatory provisions. Section 10.45(e) states that: "An interested person may request judicial review of a final decision of the Commissioner in the courts without first petitioning the Commissioner for reconsideration or for a stay of action, except that in accordance with paragraph (c) of this section, the person shall request a stay by the Commissioner under § 10.35 before requesting a stay by the court." Plaintiffs argue that they are "interested persons" and that the approval of the SNDA is a final agency action. Thus, they argue that § 10.45(e) allows them to proceed to court without first presenting their arguments to the agency.

Although plaintiffs' interpretation of the regulatory requirements has some surface appeal, it would allow " 'interested parties' to bypass the administrative remedies" and "would undermine the entire regulatory process." *Garlic v. FDA,* 783 F.Supp. 4, 5 (D.D.C.1992). Courts would constantly have to address new arguments that were never presented to the agency. The purpose of the exhaustion doctrine is "the avoidance of premature interruption of the administrative process ... to let the agency develop the necessary factual background upon which decisions should be based." *McKart v. United States,* 395 U.S. 185, 193-194, 89 S.Ct. 1657, 23 L.Ed.2d 194 (1969). "And since agency decisions are frequently of a discretionary nature or frequently require expertise, the agency should be given the first chance to exercise that discretion or to apply that expertise." *Id.* at 194, 89 S.Ct. 1657. As defendants assert here, "no administrative record of

the FDA's consideration of [plaintiffs'] arguments exists ... because plaintiffs have never submitted those challenges to the FDA." Duramed's Reply at 22.

When § 10.45(e) is read together with other applicable provisions, such as § 10.45(b), a different picture is presented that is more in keeping with the rationale underlying the exhaustion doctrine. As noted above, § 10.45(b) requires that an interested person's "request that the Commissioner take or refrain from taking any form of administrative action must first be the subject of a final administrative decision based on a petition submitted under § 10.25(a)." Together with § 10.45(e), "these provisions require a party to present its request to the agency and to receive a final decision on that request before seeking judicial review, but do not require the party to pursue an administrative appeal of that final decision before filing its lawsuit." Fed. Defs.' Mem. at 32, n. 22. The party would need a final agency decision on *its* challenge to the approval of a SNDA, but consistent with § 10.45(e) would not then have to seek "reconsideration or ... a stay" before requesting judicial review. The agency would thereby have an opportunity to apply its expertise, and courts would have developed administrative records to review.

The agency's regulations are most relevant for this challenge to the *approval* of a SNDA, but it is notable that the FDCA itself also "provides for administrative review of orders ... *denying* New Drug Applications." *Bracco Diagnostics, Inc. v. Shalala,* 963 F.Supp. 20, 30 (D.D.C.1997) (citing 21 U.S.C. § 355(h)) (emphasis added). Under the statute, "[a]n appeal may be taken by the applicant from an order of the Secretary refusing or withdrawing approval" of

a new drug application by filing a petition "in the United States court of appeals for the circuit wherein such applicant resides or has his principal place of business, or in the United States Court of Appeals for the District of Columbia Circuit." 21 U.S.C. § 355(h). The ability to appeal the denial is extended only to the applicant itself, not to interested parties such as plaintiffs. Additionally, the court of appeals will not entertain any arguments and objections to the FDA's determination "unless such objection shall have been urged before the Secretary or unless there were reasonable grounds for failure so to do." *Id.* If consideration of additional evidence is required, the court of appeals may require the applicant to present the additional evidence to the FDA so that the agency may have the opportunity to modify its order. *Id.* The citizen petition process is thus parallel to this statutory process that allows the agency to first address any objection to its action prior to judicial review. Indeed, it would be odd if the applicant were so limited in challenging the denial of its SNDA, but, as plaintiffs would have it, other "interested parties" could proceed right to federal court with a challenge to the grant of a SNDA not first raised with the FDA.

Defendants cite two opinions from this district which have discussed the exhaustion issue and have dismissed complaints as non-justiciable for failure to exhaust administrative remedies under the FDCA. In *Garlic v. FDA*, 783 F.Supp. 4 (D.D.C.1992), the plaintiffs challenged the FDA's failure to approve a specific drug as a treatment for Alzheimer's Disease. The court dismissed the plaintiffs' complaint because they had "not exhausted their administrative remedies by filing a 'citizen's petition' as required by 21 C.F.R. § 10.25(b)." *Id.* at 4. The court noted that if

it were to entertain the complaint without an appropriate administrative record addressing plaintiffs' arguments, the court would involve itself in matters "beyond both [its] expertise and its jurisdiction." *Id.* And in *National Gay Rights Advocates v. Dep't of Health & Human Serv.*, 1988 WL 43833 (D.D.C. Apr. 26, 1988), the court also dismissed the plaintiffs' complaint for failure to exhaust administrative remedies. There, plaintiffs alleged "that the FDA and NIH have engaged in improper conduct with respect to the development and approval of drugs used to treat and cure AIDS." *Id.* at *1. In dismissing the complaint, the court noted that it "should not interfere with the agency's decisionmaking by denying FDA and NIH the first opportunity to decide what action is warranted." *Id.* at *2.

The federal defendants recognize, however, that courts "have the discretion to decline to apply regulatory exhaustion in certain circumstances, such as where the plaintiff demonstrates that it would be irreparably harmed by delay, that the agency is not empowered to grant effective relief, or that the exhaustion effort would be futile." Fed. Defs.' Response to Pls.' Notice of Supp. Authority at 2 (citing *McCarthy v. Madigan*, 503 U.S. 140, 144-49, 112 S.Ct. 1081, 117 L.Ed.2d 291 (1992)); *see, e.g., Bracco Diagnostics, Inc.*, 963 F.Supp. at 31 ("Lacking a specific congressional mandate as to the plaintiffs' administrative remedy and finding plaintiffs faced with irreparable harm, the Court concludes that exhaustion of administrative remedies in the circumstances of this case is not required."). In fact, the federal defendants asset that they often do not raise the exhaustion defense when such

circumstances are present. As an example of such a situation, defendants point to *Mova Pharm. Corp. v. Shalala,* 955 F.Supp. 128, 130 (D.D.C.1997), *aff'd in part and rev'd in part,* 140 F.3d 1060 (D.C.Cir.1998), where a pharmaceutical company sued to compel the FDA to withdraw or change the effective date of its approval of a competitor's abbreviated new drug application.

Here, there are no circumstances that should lead this Court to decline to require exhaustion. Plaintiffs would not be irreparably harmed by delay. The agency is in fact empowered to grant the relief plaintiffs seek. And there is no indication that the administrative process would be futile because the agency has not yet had the opportunity to address all of plaintiffs' arguments. On the other hand, the Court should not attempt to resolve these arguments before the FDA has the opportunity to apply its expertise and a record is developed. Because the plaintiffs have failed to exhaust the administrative process mandated by regulation, dismissal of plaintiffs' amended complaint is warranted.

CONCLUSION

For the foregoing reasons, the Court concludes that plaintiffs have not demonstrated their standing to assert the claims in the amended complaint. Hence, the Court has no jurisdiction to entertain the amended complaint. Plaintiffs have also failed to exhaust their administrative remedies and have therefore failed to state a claim upon which relief can be granted. Accordingly, the Court will grant defendants' motions to dismiss. A separate order accompanies this memorandum opinion.

United States District Court for the District of Columbia

ASS'N OF AMERICAN PHYSICIANS & SURGEONS, *ET AL.*,

PLAINTIFFS,

v.

FOOD & DRUG ADMINISTRATION, *ET AL.*,

DEFENDANTS.

No. 08-5458

Decided Aug. 22, 2008

Before: JOHN D. BATES, District Judge.

ORDER

Pursuant to Fed. R. Civ. P. 59(e) and 60(b), plaintiffs Association of American Physicians & Surgeons, Inc., Concerned Women for America, Family Research Council, and Safe Drugs for Women have moved for reconsideration of the Court's March 4, 2008 memorandum opinion and order dismissing the first amended complaint. *See Ass'n of Am. Physicians & Surgeons, Inc. v. FDA*, 539 F. Supp. 2d 4, 24 (D.D.C. 2008). In that decision, the Court determined that plaintiffs lacked standing to invoke federal court jurisdiction and, in the alternative, that plaintiffs had failed to exhaust their administrative remedies. The Court will assume familiarity with the facts of this case, which are laid out in full in its earlier opinion.

"'A Rule 59(e) motion is discretionary and need not be granted unless the district court finds that there is an intervening change of controlling law, the availability of new evidence, or the need to correct a

clear error or prevent manifest injustice.'" *Ciralsky v. Cent. Intelligence Agency*, 355 F.3d 661, 671 (D.C. Cir. 2004) (quoting *Firestone v. Firestone*, 76 F.3d 1205, 1208 (D.C. Cir. 1996)); *see also Mobley v. Cont'l Cas. Co.*, 405 F. Supp. 2d 42, 45 (D.D.C. 2005) ("A motion for reconsideration . . . will not lightly be granted."). A Rule 59(e) motion "is not simply an opportunity to reargue facts and theories upon which a court has already ruled." *New York v. United States*, 880 F. Supp. 37, 38 (D.D.C. 1995). Nor is it "a vehicle for presenting theories or arguments that could have been advanced earlier." *Burlington Ins. Co. v. Okie Dokie Inc.*, 439 F. Supp. 2d 124, 128 (D.D.C. 2006); *see also Kattan v. Dist. of Columbia*, 995 F.2d 274, 276 (D.C. Cir. 1993).

A district court also "enjoys significant discretion in deciding whether to grant or deny a Rule 60(b) motion." *Computer Prof'ls for Soc. Responsibility v. U.S. Secret Serv.*, 72 F.3d 897, 903 (D.C. Cir. 1996). Based upon the large measure of discretion that is afforded district courts, "[r]elief under Rule 60(b)(1) motions is rare." *Hall v. Cent. Intelligence Agency*, 437 F.3d 94, 99 (D.C. Cir. 2006). Moreover, it is well established that Rule 60(b)(6) "relief should be only sparingly used" in "extraordinary circumstances." *Computer Prof'ls*, 72 F.3d at 903 (quoting *Good Luck Nursing Home, Inc. v. Harris*, 636 F.2d 572, 577 (D.C. Cir. 1980)).

Here, plaintiffs have mainly used their motion for reconsideration as an inappropriate vehicle to "reargue facts and theories upon which a court has already ruled." *New York*, 880 F. Supp. at 38. Indeed, for the most part, plaintiffs' forty-six page motion simply repeats every argument that was previously rejected by the Court. To the extent that plaintiffs

rehash the same theories, the Court need not repeat here its reasons for again rejecting those arguments.[1]

Upset at the Court's conclusions, plaintiffs now contend that the Court erred in failing to assume plaintiffs' merits view during the justiciability analysis. Plaintiffs repeatedly make this assertion, however, without providing any explanation to support a change in the Court's conclusions. Plaintiffs' failure to provide a convincing explanation is unsurprising because throughout the Court's analysis it was well aware that one must "assum[e] the validity of [plaintiffs'] substantive claim at the standing inquiry." *Catholic Soc. Serv. v. Shalala*, 12 F.3d 1123, 1126 (D.C. Cir. 1994). Assuming the validity of plaintiffs' claims, their alleged injuries nonetheless remain speculative, hypothetical, and conjectural. Hence, plaintiffs' argument does not change the Court's conclusion that plaintiffs' alleged injuries are insufficient to establish Article III standing.

Plaintiffs fare no better with their newly alleged "civil procedure" injury. According to plaintiffs, "litigation is a form of First Amendment petition," and they are therefore suffering a "civil procedure" injury based upon the FDA's efforts to have this case dismissed. Pls.' Mem. at 23. Defendants reject plaintiffs' novel argument as an outlandish proposition and note that "[p]laintiffs fail to cite any case that has recognized an injury or claim grounded in an agency defending itself in litigation brought by

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[1] Plaintiffs also devote substantial briefing to the issue of sovereign 1 immunity even though no defendant has ever contested the existence of a valid waiver of sovereign immunity and the Court did not rely on this as a basis for dismissal.

the allegedly injured party." Fed. Defs.' Opp'n at 8. The Court agrees that plaintiffs' new theory is without foundation and cannot satisfy Article III's standing requirements.[2]

With regard to the Court's alternative finding of exhaustion, plaintiffs again argue that their participation in the Advance Notice of Proposed Rulemaking process satisfied FDA exhaustion requirements. Although plaintiffs raised this argument before and repeatedly indicated they would provide evidence to support their contention, it is undisputed that such evidence was never produced to the Court despite ample opportunity to do so. Plaintiffs filed their initial complaint on April 12, 2007. *See* Docket No. 1. When defendants filed motions to dismiss for lack of standing and failure to exhaust administrative remedies, plaintiffs filed an amended complaint in an attempt to cure their deficiencies. *See* Docket No. 26. Defendants thereafter again filed motions to dismiss for lack of standing and failure to exhaust administrative remedies. Plaintiffs opposed the motions, participated in a motions hearing before the Court, and filed two supplemental notices following the motions hearing. *See* Docket Nos. 29, 39, 41. Never did they provide the necessary promised evidence. In light of these numerous opportunities to present all arguments, theories, and evidence, plaintiffs have not demonstrated that they can now put forward evidence that was not previously available to them.

Hence, plaintiffs' attempt to reargue rejected

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[2] Because plaintiffs still fail to satisfy Article III's standing requirements, the Court need not readdress plaintiffs' arguments regarding prudential standing.

theories is unconvincing. To the extent that plaintiffs have asserted additional arguments in support of standing or exhaustion, they could have been advanced earlier, *see Burlington Ins. Co.*, 439 F. Supp. 2d at 128, and in any event their arguments are also unpersuasive. There has been no intervening change in controlling law, nor have plaintiffs advanced new evidence not previously available to them. Finding nothing in plaintiffs' motion that warrants revisiting its prior decision, the Court will deny plaintiffs' motion for reconsideration.[3]

The remainder of plaintiffs' motion exceeds the Court's March 4, 2008 memorandum opinion and order, by seeking judgment on the merits against the FDA, its Commissioner, and intervenor-defendant Duramed Research, Inc. According to plaintiffs, "[i]f this Court reverses its jurisdictional analysis, nothing precludes resolving the merits of Counts II, IV, or VI under either the Rule 12(b)(6) or Rule 52(c) motions." Pls.' Reply at 5. Because the Court has not reversed its jurisdictional analysis, however, the Court will not address the merits of the case. *See Sinochem Int'l Co. Ltd. v. Malaysia Int'l Shipping Corp.*, 127 S.Ct. 1184, 1191 (2007) ("Without jurisdiction the court cannot proceed at all in any cause; it may not assume jurisdiction for the purpose of deciding the merits of the case.") (quotation marks

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[3] Plaintiffs currently seek leave to file 3 a second amended complaint pursuant to Fed. R. Civ. P. 15. However, plaintiffs concede that post-dismissal amendment is only warranted if plaintiffs meet "the higher standard of Rule 59(e)." Pls.' Mem. at 7 (citing *Firestone*, 76 F.3d at 1208). Because plaintiffs have not satisfied that standard, the Court will deny plaintiffs' motion for leave to amend the complaint.

and citation omitted). Therefore, plaintiffs' motion for judgment on Counts II, IV, and VI will be denied.

Accordingly, upon consideration of [45] plaintiffs' motion to alter and amend judgment, for judgment on partial findings, for reconsideration of dismissal, and for leave to file amended and supplemental complaint, and the entire record herein, and for the reasons explained above, it is hereby

ORDERED that [45] plaintiffs' motion is **DENIED.**

SO ORDERED.

/s/

JOHN D. BATES
United States District Judge

United States Court of Appeals for the District of Columbia Circuit

ASS'N OF AMERICAN PHYSICIANS & SURGEONS, *ET AL.*

APPELLANTS,

v.

FOOD & DRUG ADMINISTRATION, *ET AL.*,

APPELLEES.

No. 08-5458
Decided Apr. 6, 2009

Before: GINSBURG, ROGERS, and GARLAND, Circuit Judges.

ORDER

Upon consideration of the motions for summary affirmance, the opposition thereto, and the replies; and the motion for summary reversal, the opposition thereto, and the reply, it is

ORDERED that the motions for summary affirmance and the motion for summary reversal be denied. The merits of the parties' positions are not so clear as to warrant summary action. *See Taxpayers Watchdog, Inc. v. Stanley,* 819 F.2d 294, 297 (D.C. Cir. 1987) (per curiam).

Because the court has determined that summary disposition is not in order, the Clerk is instructed to calendar this case for presentation to a merits panel.

Per Curiam

United States Court of Appeals for the District of Columbia Circuit

ASS'N OF AMERICAN PHYSICIANS & SURGEONS, *ET AL.*

APPELLANTS,

v.

FOOD & DRUG ADMINISTRATION, *ET AL.*,

APPELLEES.

No. 08-5458
Filed on Feb. 3, 2010

Before: SENTELLE, Chief Circuit Judge, GINSBURG, HENDERSON, ROGERS, TATEL, GARLAND,* BROWN, GRIFFITH, and KAVANAUGH, Circuit Judges, and EDWARDS, Senior Circuit Judge.

ORDER

Upon consideration of appellants' amended petition for rehearing en banc, and the absence of a request by any member of the court for a vote, it is ORDERED that the petition be denied.

Per Curiam

FOR THE COURT:
Mark J. Langer, Clerk
By: /s/
Michael C. McGrail
Deputy Clerk

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* Circuit Judge Garland did not participate in this matter.

5 U.S.C. §704

Agency action made reviewable by statute and final agency action for which there is no other adequate remedy in a court are subject to judicial review. A preliminary, procedural, or intermediate agency action or ruling not directly reviewable is subject to review on the review of the final agency action. Except as otherwise expressly required by statute, agency action otherwise final is final for the purposes of this section whether or not there has been presented or determined an application for a declaratory order, for any form of reconsideration, or, unless the agency otherwise requires by rule and provides that the action meanwhile is inoperative, for an appeal to superior agency authority.

FFDCA §503(b), 21 U.S.C. §353(b)

(1) A drug intended for use by man which--

(A) because of its toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use, is not safe for use except under the supervision of a practitioner licensed by law to administer such drug; or

(B) is limited by an approved application under section 355 of this title to use under the professional supervision of a practitioner licensed by law to administer such drug;

(C) Redesignated (B)

shall be dispensed only (i) upon a written prescription of a practitioner licensed by law to administer such drug, or (ii) upon an oral prescription of such practitioner which is reduced promptly to writing and filed by the pharmacist, or

(iii) by refilling any such written or oral prescription if such refilling is authorized by the prescriber either in the original prescription or by oral order which is reduced promptly to writing and filed by the pharmacist. The act of dispensing a drug contrary to the provisions of this paragraph shall be deemed to be an act which results in the drug being misbranded while held for sale.

(2) Any drug dispensed by filling or refilling a written or oral prescription of a practitioner licensed by law to administer such drug shall be exempt from the requirements of section 352 of this title, except paragraphs (a), (i)(2) and (3), (k), and (l), and the packaging requirements of paragraphs (g), (h), and (p), if the drug bears a label containing the name and address of the dispenser, the serial number and date of the prescription or of its filling, the name of the prescriber, and, if stated in the prescription, the name of the patient, and the directions for use and cautionary statements, if any, contained in such prescription. This exemption shall not apply to any drug dispensed in the course of the conduct of a business of dispensing drugs pursuant to diagnosis by mail, or to a drug dispensed in violation of paragraph (1) of this subsection.

(3) The Secretary may by regulation remove drugs subject to section 355 of this title from the requirements of paragraph (1) of this subsection when such requirements are not necessary for the protection of the public health.

(4)(A) A drug that is subject to paragraph (1) shall be deemed to be misbranded if at any time prior to dispensing the label of the drug fails to bear, at a minimum, the symbol "Rx only".

(B) A drug to which paragraph (1) does not apply shall be deemed to be misbranded if at any time prior to dispensing the label of the drug bears the symbol described in subparagraph (A).

(5) Nothing in this subsection shall be construed to relieve any person from any requirement prescribed by or under authority of law with respect to drugs now included or which may hereafter be included within the classifications stated in sections 4721, 6001, and 6151 of Title 26, or to marihuana as defined in section 4761 of Title 26.

FFDCA §505c(g)(2), 21 U.S.C. §355c(g)(2)

If, on or after September 27, 2007, the Secretary makes a determination that a pediatric assessment conducted under this section does or does not demonstrate that the drug that is the subject of such assessment is safe and effective in pediatric populations or subpopulations, including whether such assessment results are inconclusive, the Secretary shall order the label of such product to include information about the results of the assessment and a statement of the Secretary's determination.

FFDCA §505c(h)(1)-(2), 21 U.S.C. §355c(h)(1)-(2)

(1) In general

Not later than 210 days after the date of submission of a pediatric assessment under this section, the Secretary shall make available to the public in an easily accessible manner the medical, statistical, and clinical pharmacology reviews of such pediatric assessments, and shall post such assessments on the Web site of the Food and Drug Administration.

(2) Dissemination of information regarding labeling changes

Beginning on September 27, 2007, the Secretary shall require that the sponsors of the assessments that result in labeling changes that are reflected in the annual summary developed pursuant to subsection (f)(6)(H) of this section distribute such information to physicians and other health care providers.

Pediatric Research Equity Act of 2007, Pub. L. No. 110-85, §402(b)(2), 121 Stat. 866, 875 (Sept. 27, 2007)

(2) CERTAIN ASSESSMENTS AND WAIVER REQUESTS.—An assessment pending on or after the date that is 1 year prior to the date of the enactment of this Act shall be subject to the tracking and disclosure requirements established under such section 505B, as in effect on or after such date of enactment, except that any such assessments submitted or waivers of such assessments requested before such date of enactment shall not be subject to subsections (a)(4)(C), (b)(2)(C), (f)(6)(F), and (h) of such section 505B.

21 C.F.R. §10.3(a)

(a) The following definitions apply in this part and Parts 12, 13, 14, 15, 16, and 19:

* * *

Interested person or any person who will be adversely affected means a person who submits a petition or comment or objection or otherwise asks to participate in an informal or formal administrative proceeding or court action.

21 C.F.R. §10.25(a)

(a) An interested person may petition the Commissioner to issue, amend, or revoke a regulation or order, or to take or refrain from taking any other form of administrative action. A petition must be either: (1) In the form specified in other applicable FDA regulations, e.g., the form for a color additive petition in § 71.1, for a food additive petition in § 171.1, for a new drug application in § 314.50, for a new animal drug application in § 514.1, or (2) in the form for a citizen petition in § 10.30.

21 C.F.R. §10.35(d)

(d) Neither the filing of a petition for a stay of action nor action taken by an interested person in accordance with any other administrative procedure in this part or in any other section of this chapter, e.g., the filing of a citizen petition under § 10.30 or a petition for reconsideration under § 10.33 or a request for an advisory opinion under § 10.85, will stay or otherwise delay any administrative action by the Commissioner, including enforcement action of any kind, unless one of the following applies:

(1) The Commissioner determines that a stay or delay is in the public interest and stays the action.

(2) A statute requires that the matter be stayed.

(3) A court orders that the matter be stayed.

21 C.F.R. §10.45(a)-(b), (e)

(a) This section applies to court review of final administrative action taken by the Commissioner, including action taken under §§ 10.25 through 10.40

and § 16.1(b), except action subject to § 10.50 and Part 12.

(b) A request that the Commissioner take or refrain from taking any form of administrative action must first be the subject of a final administrative decision based on a petition submitted under § 10.25(a) or, where applicable, a hearing under § 16.1(b) before any legal action is filed in a court complaining of the action or failure to act. If a court action is filed complaining of the action or failure to act before the submission of the decision on a petition under § 10.25(a) or, where applicable, a hearing under § 16.1(b), the Commissioner shall request dismissal of the court action or referral to the agency for an initial administrative determination on the grounds of a failure to exhaust administrative remedies, the lack of final agency action as required by 5 U.S.C. 701 et seq., and the lack of an actual controversy as required by 28 U.S.C. 2201.

* * *

(e) An interested person may request judicial review of a final decision of the Commissioner in the courts without first petitioning the Commissioner for reconsideration or for a stay of action, except that in accordance with paragraph (c) of this section, the person shall request a stay by the Commissioner under § 10.35 before requesting a stay by the court.

21 C.F.R. §10.85

* * *

(d) A statement of policy or interpretation made in the following documents, unless

subsequently repudiated by the agency or overruled by a court, will constitute an advisory opinion:

(1) Any portion of a Federal Register notice other than the text of a proposed or final regulation, e.g., a notice to manufacturers or a preamble to a proposed or final regulation.

* * *

(e) An advisory opinion represents the formal position of FDA on a matter and except as provided in paragraph (f) of this section, obligates the agency to follow it until it is amended or revoked. The Commissioner may not recommend legal action against a person or product with respect to an action taken in conformity with an advisory opinion which has not been amended or revoked.

21 C.F.R. §310.200

(a) Duration of prescription requirement. Any drug limited to prescription use under section 503(b)(1)(B) of the act remains so limited until it is exempted as provided in paragraph (b) or (e) of this section.

(b) Prescription-exemption procedure for drugs limited by a new drug application. Any drug limited to prescription use under section 503(b)(1)(B) of the act shall be exempted from prescription-dispensing requirements when the Commissioner finds such requirements are not necessary for the protection of the public health by reason of the drug's toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use, and he finds that the drug is safe and effective for use in self-medication as directed in proposed labeling. A proposal to exempt a drug from the

prescription-dispensing requirements of section 503(b)(1)(B) of the act may be initiated by the Commissioner or by any interested person. Any interested person may file a petition seeking such exemption, which petition may be pursuant to Part 10 of this chapter, or in the form of a supplement to an approved new drug application.

(c) New drug status of drugs exempted from the prescription requirement. A drug exempted from the prescription requirement under the provisions of paragraph (b) of this section is a "new drug" within the meaning of section 201(p) of the act until it has been used to a material extent and for a material time under such conditions except as provided in paragraph (e) of this section.

(d) Prescription legend not allowed on exempted drugs. The use of the prescription caution statement quoted in section 503(b)(4) of the act, in the labeling of a drug exempted under the provisions of this section, constitutes misbranding. Any other statement or suggestion in the labeling of a drug exempted under this section, that such drug is limited to prescription use, may constitute misbranding.

(e) Prescription-exemption procedure of OTC drug review. A drug limited to prescription use under section 503(b)(1)(B) of the act may also be exempted from prescription-dispensing requirements by the procedure set forth in § 330.13 of this chapter.